

EXHIBIT A



**AFTAB PUREVAL
HAMILTON COUNTY CLERK OF COURTS**

COMMON PLEAS DIVISION

**ELECTRONICALLY FILED
May 30, 2019 09:13 PM
AFTAB PUREVAL
Clerk of Courts
Hamilton County, Ohio
CONFIRMATION 850067**

TERESA A BEHYMER

A 1902638

vs.

ABBOTT LABORATORIES

FILING TYPE: CLASSIFICATION

PAGES FILED: 1

EFR200



COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

CLASSIFICATION FORM
WWW.COURTCLERK.ORG

AFTAB PUREVAL
CLERK OF COURTS

CASE NUMBER: _____ PLAINTIFF: Teresa A. Behymer

PURSUANT TO SUPERINTENDENCE RULE 4, THIS CASE WAS ORIGINALLY FILED AND DISMISSED

UNDER CASE NUMBER: _____ BY JUDGE _____

PLEASE INDICATE CLASSIFICATION INTO WHICH THIS CASE FALLS (please only check one):

- | | |
|--|---|
| <input type="checkbox"/> Other Tort – C360 | <input type="checkbox"/> Other Civil – H700-34 |
| <input type="checkbox"/> Personal Injury – C310 | <input type="checkbox"/> Appropriation – H710 |
| <input type="checkbox"/> Wrongful Death – C320 | <input type="checkbox"/> Accounting – H720 |
| <input type="checkbox"/> Vehicle Accident – C370 | <input type="checkbox"/> Beyond Jurisdiction – 730 |
| <input type="checkbox"/> Professional Tort – A300 | <input type="checkbox"/> Breach of Contract – 740 |
| <input type="checkbox"/> Personal Injury – A310 | <input type="checkbox"/> Cancel Land Contract – 750 |
| <input type="checkbox"/> Wrongful Death – A320 | <input type="checkbox"/> Change of Venue – H760 |
| <input type="checkbox"/> Legal Malpractice – A330 | <input type="checkbox"/> Class Action – H770 |
| <input type="checkbox"/> Medical Malpractice – A340 | <input type="checkbox"/> Convey Declared Void – H780 |
| <input checked="" type="checkbox"/> Product Liability – B350 | <input type="checkbox"/> Declaratory Judgment – H790 |
| <input type="checkbox"/> Personal Injury – B310 | <input type="checkbox"/> Discharge Mechanics Lien – H800 |
| <input type="checkbox"/> Wrongful Death – B320 | <input type="checkbox"/> Dissolve Partnership – H810 |
| <input type="checkbox"/> Worker's Compensation | <input type="checkbox"/> CONSUMER SALES ACT (1345 ORC) – H820 |
| <input type="checkbox"/> Non-Compliant Employer – D410 | <input type="checkbox"/> Check here if relief includes declaratory judgment, injunction or class action recovery – H825 |
| <input type="checkbox"/> Appeal – D420 | <input type="checkbox"/> Habeas Corpus – H830 |
| <input type="checkbox"/> Administrative Appeals – F600 | <input type="checkbox"/> Injunction – H840 |
| <input type="checkbox"/> Appeal Civil Service – F610 | <input type="checkbox"/> Mandamus – H850 |
| <input type="checkbox"/> Appeal Motor Vehicle – F620 | <input type="checkbox"/> On Account – H860 |
| <input type="checkbox"/> Appeal Unemployment – F630 | <input type="checkbox"/> Partition – H870 |
| <input type="checkbox"/> Appeal Liquor – F640 | <input type="checkbox"/> Quiet Title – H880 |
| <input type="checkbox"/> Appeal Taxes – F650 | <input type="checkbox"/> Replevin – H890 |
| <input type="checkbox"/> Appeal Zoning – F660 | <input type="checkbox"/> Sale of Real Estate – H900 |
| <input type="checkbox"/> Certificate of Qualification – H600 | <input type="checkbox"/> Specific Performance – 910 |
| | <input type="checkbox"/> Restraining Order – H920 |
| | <input type="checkbox"/> Testimony – H930-21 |
| | <input type="checkbox"/> Environmental – H940 |
| | <input type="checkbox"/> Cognovit – H950 |
| | <input type="checkbox"/> Menacing by Stalking – H960 |
| | <input type="checkbox"/> Repo Title – Transfer of Title Only – 970 |
| | <input type="checkbox"/> Repo Title – With Money Claim – H980 |
| | <input type="checkbox"/> Injunction Sexual Predator – 990 |
| | <input type="checkbox"/> SB 10 – Termination – H690 |
| | <input type="checkbox"/> SB 10 – Reclassification – H697 |

DATE: 5/30/19

ATTORNEY (PRINT): John D. Holschuh, Jr.

OHIO SUPREME COURT NUMBER: 0019327



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**FILING TYPE: INITIAL FILING (OUT OF COUNTY) WITH JURY
DEMAND**

PAGES FILED: 77

EFR200



VERIFY RECORD

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

This Document Relates To:

TERESA A. BEHYMER
29 Richmond Drive
Westchester, OH 45069

Plaintiff,

vs.

ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064

**ASTRAZENECA PHARMACEUTICALS
LP**
1800 Concord Pike
Wilmington, Delaware 19850

ASTRAZENECA LP
1800 Concord Pike
Wilmington, Delaware 19850

**GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC**
184 Liberty Corner Road
Warren, New Jersey 07059

**MERCK & CO., INC. D/B/A MERCK,
SHARP & DOHME CORPORATION**
One Merck Drive
Whitehouse Station, New Jersey 08889

NOVARTIS CORPORATION
Lichtstrasse 35, CH-4056
Basel, Switzerland

**NOVARTIS PHARMACEUTICALS
CORPORATION**
One Health Plaza
East Hanover, New Jersey 07936

CASE NO:

Judge

**COMPLAINT WITH JURY
DEMAND ENDORSED HEREON**

NOVARTIS INSTITUTES FOR

BIOMEDICAL RESEARCH, INC.

250 Massachusetts Avenue
Cambridge, Massachusetts 02139

**NOVARTIS VACCINES AND
DIAGNOSTICS, INC.**

1 Health Plaza
East Hanover, New Jersey 07936

NOVARTIS CONSUMER HEALTH, INC.

200 Kimball Drive
Parsippany, New Jersey 07054

PFIZER, INC.

235 East 42nd Street
New York, New York 10017

THE PROCTER & GAMBLE COMPANY

1 Procter & Gamble Plaza
Cincinnati, Ohio 45202

**THE PROCTER & GAMBLE
MANUFACTURING COMPANY**

3875 Reservoir Road
Lima, Ohio 45801

**TAKEDA PHARMACEUTICALS USA,
INC.**

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICALS
AMERICA, INC.**

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA DEVELOPMENT CENTER
AMERICAS, INC. F/K/A TAKEDA
GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC.**

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICAL
COMPANY LIMITED**

1-1, Doshomachi 4-chome
Chuoku, Osaka, Japan

Defendants.

.....

COMES NOW, Plaintiff(s), Teresa A. Behymer, by and through the undersigned counsel, and brings this Complaint against Abbott Laboratories; AstraZeneca Pharmaceuticals LP (“AZ Pharm”); AstraZeneca LP (“AZ LP”); GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (“GSK LLC”); Merck & Co., Inc. d/b/a Merck, Sharp & Dohme Corporation (“Merck”); Novartis Corporation (“Novartis Corp”); Novartis Pharmaceuticals Corporation (“NPC”); Novartis Institutes for Biomedical Research, Inc. (“NIBRI”); Novartis Vaccines and Diagnostics, Inc. (“NV&D”); Novartis Consumer Health, Inc. (“NCHI”); Pfizer, Inc. (“Pfizer”); The Procter & Gamble Company (“P&G”);, The Procter & Gamble Manufacturing Company (“PGM”); Takeda Pharmaceuticals USA, Inc. (“TPUSA”); Takeda Pharmaceuticals America, Inc. (“TPA”); Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. (“TDC Americas”); Takeda Pharmaceutical Company Limited (“TPC”), hereinafter collectively referred to as “Defendants” and for their Complaint and Jury Demand allege as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants’ defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys’ investigative efforts to date, regarding Defendants’ prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, “the PPI Products” or “PPIs”).

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

3. As more particularly set forth herein, the Plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to, Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

PARTIES, JURISDICTION & VENUE

6. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court. The amount in controversy exceeds TWENTY- FIVE THOUSAND DOLLARS (\$25,000.00), exclusive of interest and costs, the jurisdictional minimum of this Court.

I. PLAINTIFF

7. Plaintiff, Teresa A. Behymer, resides in Westchester, Ohio and resided in Westchester, Ohio at all times relevant.

a. Plaintiff, Teresa A. Behymer ingested the following PPI products sold by the Defendants from at least approximately January 2014 to December 2018:,
Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix, Plaintiff has suffered and was treated for, Chronic Kidney Disease (“CKD”), in approximately August 2016 with related sequelae.

II. DEFENDANTS

8. Defendant Abbott Laboratories (“Defendant Abbott”) is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

9. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

10. Defendant Abbott manufactures and markets Prevacid in the United States.

11. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

12. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

13. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

14. Defendant AstraZeneca Pharmaceuticals LP (“AZ Pharm”) is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

15. Defendant AstraZeneca LP ("AZ LP") is, and at all times relevant to this action, has been a limited partnership organized under the laws of Delaware having a principal place of business in Delaware, whose ultimate parent company is AstraZeneca PLC.

16. Defendants AZ Pharm and AZ LP are referred to collectively herein as "AZ Defendants."

17. Each of the AZ Defendants was the agent and employee of the other AZ Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other AZ Defendants' actual and implied permission, consent, authorization and approval.

18. The AZ Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

19. As a part of their business and at all relevant times, the AZ Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

20. In 1982, the AZ Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

21. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

22. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

23. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec which, by the year 2000, was the most widely prescribed drug in the world.

24. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

25. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

26. In an agreement reached in December 1997, the AstraZeneca Defendants entered into a co-promotion agreement with the Procter & Gamble Defendants granting the Procter & Gamble Defendants the right to market Prilosec.

27. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec and the Procter & Gamble Defendants market and sell Prilosec.

28. Pursuant to the terms of the co-promotion agreement, the Procter & Gamble Defendants marketed and sold Prilosec from at least December 8, 1997 through January 12, 2001.

29. In 2006, the FDA approved New Drug Application (“NDA”) 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

30. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

31. Defendant AZ LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

32. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

33. In anticipation of the expiration of the patent for prescription Prilosec, the AZ Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

34. In December 1999, Defendant AZ Pharm submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

35. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

36. Defendant AZ Pharm is also the holder of approved NDAs 021957 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

37. The AZ Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

38. In 2003, the AZ Defendants spent \$260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

39. The AZ Defendants have transacted and conducted business related to PPI products in each of the States and Territories of the United States.

40. The AZ Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was \$2.7 billion and world-wide was \$3.9 billion.

41. The AZ Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived

States related to PPIs.

42. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

43. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, pursuant to an agreement with the Novartis Defendants, obtained the rights to market and sell the over-the-counter medication Prevacid 24Hr.

44. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, in collaboration and amongst themselves, designed and developed Prevacid 24HR.

45. As a part of their business and at all relevant times, Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR products.

46. Defendant GSK Consumer Healthcare (US) IP LLC is the holder of approved NDA 022327 for Prevacid 24HR.

47. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC manufacture and market Prevacid 24HR in the United States.

48. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

49. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

50. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have expected or should have expected their acts to have consequence within each of the States and

each of the States and Territories of the United States related to Prevacid 24HR.

51. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter “Defendant Merck”) is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

52. In 1982, Defendant Merck entered into an agreement with the AZ Defendants, under the terms of which Defendant Merck developed and marketed the AZ Defendants’ products, including Nexium and Prilosec products, under a royalty-bearing license.

53. In 1993, Merck’s total sales of the AstraZeneca Defendants’ products reached a level that triggered the first step in the establishment of a joint venture business (the “Joint Venture”) in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants’ products.

54. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

55. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

56. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

57. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

58. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

59. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

60. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

61. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

62. Defendant Merck manufactures and markets Nexium products in the United States.

63. Defendant Merck manufactures and markets Prilosec products in the United States.

64. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

65. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

66. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

67. Defendant Novartis Corporation is and, at all times relevant to this action, has been a New York corporation having a principal place of business in East Hanover, NJ.

68. Defendant Novartis Pharmaceuticals Corporation is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, NJ 07936.

69. Defendant Novartis Institutes for Biomedical Research, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business at 250 Massachusetts Avenue, Cambridge, MA 02139.

70. Defendant Novartis Vaccines and Diagnostics, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business in East Hanover, NJ.

71. Defendant Novartis Corporation is the parent/holding company of Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

72. At all relevant times, Defendant Novartis Corporation has exercised and exercises dominion and control over Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

73. Defendants Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc. are herein referred to collectively as “Novartis Defendants.”

74. Each of the Novartis Defendants was the agent and employee of the other Novartis Defendants, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Novartis Defendants’ actual and implied permission, consent, authorization and approval.

75. In 2005, the Novartis Defendants obtained the rights to market the over-the-counter version of Prevacid, Prevacid 24HR.

76. As part of their business and at all relevant times, the Novartis Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR.

77. The Novartis Defendants, in collaboration amongst themselves, designed and developed the Prevacid 24 HR.

78. Defendant Novartis Pharmaceuticals Corporation has been the holder of approved NDA 022327 for Prevacid 24HR.

79. The Novartis Defendants manufacture and market Prevacid 24HR in the United States.

80. The Novartis Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

81. The Novartis Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

82. The Novartis Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

83. Defendant Pfizer Inc. is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 235 East 42nd Street, New York, NY 10017.

84. As a part of their business and at all relevant times, Defendant Pfizer Inc. has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of the drugs Protonix (pantoprazole) and Nexium 24HR.

85. In or about 2012, Defendant Pfizer Inc. entered into a marketing agreement with the AstraZeneca Defendants whereby Defendant Pfizer Inc. acquired the rights to market Nexium 24HR products.

86. On or about March 28, 2014, Defendant Pfizer Inc., in collaboration with and pursuant to its marketing agreement with the AstraZeneca Defendants, was granted FDA approval to market Nexium 24HR products.

87. Defendant Pfizer Inc. makes Nexium 24HR available for purchase in the United States in and around 2014 and continues to manufacture and market Nexium 24HR in the United States.

88. Defendant Pfizer Inc. manufactures and markets Protonix in the United States.

89. Defendant Pfizer Inc. has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

90. Defendant Pfizer Inc. has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

91. Defendant Pfizer Inc. has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

92. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

93. Defendant The Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

94. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests of Defendant The Procter & Gamble Manufacturing Company.

95. Defendant The Procter & Gamble Company and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

96. Each of the Procter & Gamble Defendants was the agent and employee of the Other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant’s actual and implied permission, consent, authorization and approval.

97. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

98. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

99. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

100. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

101. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

102. The Procter & Gamble Defendants made Prilosec OTC available for purchase in the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

103. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

104. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

105. The Procter & Gamble Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prilosec OTC.

106. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

107. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

108. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

109. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

110. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

111. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

112. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

113. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

114. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

115. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid, Prevacid 24HR and Protonix products.

116. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid, Prevacid 24HR and Protonix products.

117. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

118. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

119. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

120. The Takeda Defendants manufacture and market each of these Protonix formulations in the United States.

Products in each of the States and Territories of the United States.

122. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

123. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

124. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

125. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

127. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

128. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from

prescription medication in the United States each year.

129. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

130. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

131. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

B. PPI Products Cause Severe Kidney Injuries

132. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in *The American Journal of Medicine*.

133. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

134. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

135. In 2006, researchers at the Yale School of Medicine conducted a case series published in the *International Society of Nephrology's Kidney International* finding that PPI Product use, by way of AIN, left most patients “with some level of chronic kidney disease.”

136. In 2007, F. Sierra et al. published an article in the *Journal of Alimentary Pharmacology and Therapeutics*, titled, “Systematic review: proton pump inhibitor-associated

inhibitors is associated with interstitial nephritis.

137. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, “where PPI-induced AIN is disproportionately present in the database.” Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

138. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen’s Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

139. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

140. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

141. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

142. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

143. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

144. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

145. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

146. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

147. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

148. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

149. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

150. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

151. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ii. PPI-Induced Acute Kidney Injury (“AKI”)

152. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

153. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

154. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

155. Currently, the product labeling for PPI Products, both prescription and over-the counter, does not contain any warning regarding the increased risk of AKI.

156. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

iii. PPI-Induced Chronic Kidney Disease (“CKD”)

157. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

158. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

159. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

160. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

161. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

162. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

163. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int’l 1482 (2017).

164. To date, the labeling for Defendants’ PPI Products lack adequate risk information about CKD.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

166. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

167. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

168. Because PPI Products work by preventing the acidification of the stomach’s contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies’ acid production increases beyond their pre-PPI treatment levels.

169. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

170. After Plaintiff’s discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

171. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

172. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

173. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

D. Safer Alternatives to PPIs

174. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as "H₂ Blockers") that were developed in the late 1960s. H₂ Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H₂ Blockers include Zantac, Pepcid and Tagamet. H₂ Blockers are not associated with an increased risk of kidney injuries.

175. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

176. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

E. Injuries Resulting from PPI Products

177. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

178. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

179. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

180. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

181. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

182. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and

still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

183. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

184. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

185. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

186. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

187. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

188. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

189. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

190. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

191. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

192. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

193. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

194. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

195. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

G. Defendants Violations of Federal Law

196. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

197. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because, among other things, their labeling is false or misleading;

b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR § 201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR § 201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;

Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

199. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

200. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

201. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

202. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the

proximate result of the wrongful acts and omissions of the Defendants.

203. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

204. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

205. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

206. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

207. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

208. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

209. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

210. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

211. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

CAUSES OF ACTION

COUNT I **STRICT PRODUCT LIABILITY**

212. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

213. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

214. At the time of the Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

215. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

216. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

217. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including the Plaintiff.

218. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

219. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

220. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

222. At the time, the Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

223. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

224. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

225. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

226. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

227. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

228. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

229. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

230. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

231. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

232. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

233. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

234. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

similar condition as they were when they left the possession of Defendants.

236. Plaintiff did not misuse or materially alter the PPI Products.

237. Defendants are strictly liable for the Plaintiff's injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

238. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

239. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

240. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

241. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

242. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, the Plaintiff, and/or the Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, the Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

STRICT PRODUCT LIABILITY –DESIGN DEFECT

243. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. The Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

244. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

245. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use,

sustained by Plaintiff.

246. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

247. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

248. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

249. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

250. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

251. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

252. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

253. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

higher than necessary.

255. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiff specifically were not aware of these risks, nor would they expect such risks.

256. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with the design or formulation of the PPI Products, as defined by Ohio Rev. Code. §§ 2307.75(C), or they were more dangerous than an ordinary consumer would expect.

257. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, as defined at Ohio Rev. Code. §§ 2307.75(B)(1)-(5), include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective

and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury, as defined at Ohio Rev. Code §§ 2307.75(B)(4), specifically, the risk of kidney injuries.

- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

258. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

259. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

260. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

261. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

262. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

263. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the

damages.

264. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

265. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

266. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

267. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

268. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

269. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

270. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

271. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

negligently formulated by the Defendants in disregard of the known risk of kidney injury.

272. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

273. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff's injuries and damages.

274. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

275. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

276. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

277. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

279. The defective nature of the PPI Products was a substantial factor in causing Plaintiff's injuries.

280. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

281. Defendants' conduct, as described herein, was extreme and outrageous.

282. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

283. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

284. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased

of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

285. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

286. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

287. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

288. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

289. The risks of PPI Products were not open and obvious, as defined at Ohio Rev. Code Code §§ 2307.76(B).

290. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

291. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

292. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

293. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

294. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

295. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

296. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

297. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

298. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

299. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

300. Had Plaintiff and/or her healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

301. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

302. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

303. Plaintiff and her healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

304. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

305. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

306. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

307. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

Plaintiff's injuries.

309. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

310. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

311. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

312. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

314. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

315. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

316. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;

- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;

- regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
 - m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
 - n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
 - o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
 - p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
 - q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
 - r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
 - s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;

- PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
 - v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
 - w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
 - x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
 - y. Failing to use due care under the circumstances; and
 - z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

317. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

318. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

319. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

320. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

321. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

322. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

323. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

324. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

325. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

326. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff,

knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
NEGLIGENCE PER SE

327. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

328. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

329. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

330. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

331. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

332. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

333. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

334. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

336. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

337. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

338. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

339. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

340. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

341. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

342. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure caused by the use of the PPI Products.

343. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

344. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

345. Defendants are strictly liable for the Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

346. As a direct and proximate result of Defendants' wrongful actions and failure to test, the Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

347. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

348. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of PPI Products and made representations regarding the character or quality of PPI Products including but not limited to the fact that PPI Products were safe and effective in its ordinary use.

349. The PPI Products manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

350. These material misrepresentations made by the Defendants were false.

351. Plaintiff justifiably relied upon Defendants' representations regarding PPI Products.

352. Upon information and belief, the warnings provided to those who chose to use the PPI Products, including the Plaintiff were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

353. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer

§ 2307.73(A).

354. As a direct and proximate result of the foregoing, Plaintiff are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

355. Further, as a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries; and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

357. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

358. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment

serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

359. Defendants expressly warranted that their PPI Products were safe and effective to use.

360. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

361. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

362. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

363. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

364. Defendants breached their express warranty in one or more of the following ways:

- a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

- b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
- c. Defendants failed to adequately test their PPI Products; and,
- d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

365. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

366. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

367. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

368. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

369. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

370. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

372. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

373. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

374. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

375. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the

including the law of the Plaintiff's resident State.

377. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

378. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

379. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

380. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

381. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

382. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

383. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

384. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

385. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

386. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

387. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

388. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

389. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

NEGLIGENT MISREPRESENTATION

390. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

391. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

392. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

393. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and her healthcare providers, as to the health risks and consequences of the use of their PPI Products.

394. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

395. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demands for, as well as the ultimate prescription, purchase and use of their PPI Products.

396. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

397. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

398. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

399. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

400. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff,

knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
FRAUD AND FRAUDULENT MISREPRESENTATION

401. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

402. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

403. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

404. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

406. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

407. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

408. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

409. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

410. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

411. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

412. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

413. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants

public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
GROSS NEGLIGENCE

414. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

415. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

416. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which

in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIII **FRAUDULENT CONCEALMENT**

417. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

418. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

419. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

420. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

422. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

423. Plaintiff and/or her healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

424. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

425. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

426. Defendants also had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

427. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

428. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

The Defendants to provide an adequate warning to the Plaintiff.

430. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

431. The PPI Products were improperly marketed to the Plaintiff and/or her healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

432. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

433. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and the Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

434. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

435. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

436. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

437. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

438. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

439. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

440. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

441. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous.

Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES**

442. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

443. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

444. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, Ohio Rev. Code Ann. §§ 1345.01.

445. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

446. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

/s/ John D. Holschuh, Jr.

John D. Holschuh, Jr. (0019327)

Brian P. O'Connor (0086646)

John D. Holschuh III (0095377)

SANTEN & HUGHES

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-and-

/s/ Paul J. Pennock (Pro hac vice to be filed)

Paul J. Pennock

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ppennock@weitzlux.com

ATTORNEYS FOR PLAINTIFF

JURY DEMAND

TAKE NOTICE that the Plaintiff hereby demands a trial by jury on all issues triable.

/s/ John D. Holschuh, Jr.

John D. Holschuh Jr. (0019327)

658675.3

**IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A. BEHYMER

Plaintiff,

VS.

ABBOTT LABORATORIES, *et al.*

Case No. A 1902638

Judge:

**DEFENDANTS' MOTION FOR AN EXTENSION OF TIME TO ANSWER OR
OTHERWISE RESPOND TO PLAINTIFF'S COMPLAINT**

The Procter & Gamble Company and The Procter & Gamble Manufacturing Company (collectively, the “Procter & Gamble Defendants”), by and through their undersigned counsel, hereby file this Motion for an Extension of Time to Answer or Otherwise Respond to Plaintiff’s Complaint. In support of this motion, the Procter & Gamble Defendants state:

The instant matter is one of 76 cases filed on May 30 and 31, 2019 against various defendants, including several Procter & Gamble entities (hereinafter “P&G”)¹, asserting injuries allegedly sustained from using various proton pump inhibitor (“PPI”) medications. Each of these complaints runs in excess of 70 pages and contains between 350 to more than 500 paragraphs of allegations. To the extent service as to particular P&G entities has occurred in the 76 cases, the complaints were served between June 5, 2019 and June 11, 2019. Accordingly, the responsive pleadings to a number of these complaints are currently due immediately before the 4th of July holiday (July 3, 2019), while the remaining ones would all be due immediately after the holiday (July 8 and 9, 2019). The responsive pleading deadline in this instant matter is currently July 8, 2019.

¹ All of the cases name The Procter & Gamble Company and The Procter & Gamble Manufacturing Company fraction of the cases also name The Procter & Gamble Distributing LLC.



Due to the burdens of responding to so many voluminous complaints in such a short time and because many people, including P&G's lead counsel in this litigation, will be traveling over the 4th of July holiday, counsel for P&G contacted Plaintiffs' Ohio counsel requesting an extension to file P&G's responsive pleadings in these matters. But, after conferring with his out-of-state lead counsel, Plaintiffs' Ohio counsel advised us that Plaintiffs would not agree to any extensions whatsoever.

In light of the foregoing, the Procter & Gamble Defendants hereby move this Court for a 28-day extension to answer or otherwise plead in response to Plaintiff's voluminous complaint in this matter.² A proposed order granting this Motion is being filed simultaneously.

Respectfully Submitted,

/s/ Emily S. Prem

Emily S. Prem (0093988)

ULMER & BERNE LLP

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***Counsel for Defendants The Procter & Gamble
Company and The Procter & Gamble
Manufacturing Company***

² Per Local Rule 12 the parties could have effectuated a 28-day extension by stipulation without troubling the Court if Plaintiffs had been agreeable.

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing document was served
this 26th day of June, 2019 by United States First Class Mail, postage prepaid, upon the following:

John D. Holschuh, Jr.
Brian P. O'Connor
John D. Holschuh III
SANTEN & HUGHES
600 Vine Street, Suite 2700
Cincinnati, OH 45202
Counsel for Plaintiffs

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064
Defendant

AstraZeneca Pharmaceuticals LP
AstraZeneca LP
1800 Concord Pike
Wilmington, Delaware 19850
Defendants

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
184 Liberty Corner Road
Warren, New Jersey 07059
Defendant

Merck & Co., Inc. d/b/a Merck, Sharp, & Dohme Corp.
One Merck Drive
Whitehouse Station, New Jersey 08889
Defendant

Novartis Corporation
Novartis Pharmaceuticals Corporation
Novartis Institutes for Biomedical Research, Inc.
Novartis Vaccines and Diagnostics, Inc.
Novartis Consumer Health, Inc.
One Health Plaza
East Hanover, NJ 07936
Defendants

Pfizer, Inc.
235 East 42nd Street
New York, New York 10017

Defendant

Takeda Pharmaceuticals USA, Inc.
Takeda Development Center Americas, Inc.
One Takeda Parkway
Deerfield, Illinois 60015

Defendants

/s/ Emily S. Prem

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A BEHYMER,

Plaintiff,

v.

**ASTRAZENECA
PHARMACEUTICALS LP, et al.,**

:
:
:
:
:
:
:
:
:
:

Civil Action No.: A1902638

Defendants.

**DEFENDANTS' MOTION FOR AN EXTENSION OF TIME TO ANSWER OR
OTHERWISE RESPOND TO PLAINTIFF'S COMPLAINT**

AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Merck Sharp & Dohme Corporation, incorrectly named as Merck & Co., Inc. d/b/a Merck Sharp & Dohme Corporation, (collectively, the "Movants"), by and through their undersigned counsel, hereby move for an extension of time to answer or otherwise respond to Plaintiff's Complaint.

The instant matter is one of 76 cases filed on May 30 and 31, 2019 against various defendants, including the Movants, asserting injuries allegedly sustained from using various proton pump inhibitor ("PPI") medications. Each of these complaints runs in excess of 70 pages and contains between 350 to more than 500 paragraphs of allegations. To the extent service as to Movants has occurred in the 76 cases, the complaints were served between June 6, 2019 and June 11, 2019. Accordingly, the responsive pleadings to a number of these complaints are currently due immediately after the 4th of July holiday (July 5, 8 and 9, 2019).



VERIFY RECORD

Due to the burdens of responding to so many voluminous complaints in such a short time, particularly given the 4th of July holiday, the undersigned contacted Plaintiffs' Ohio counsel to request an extension to move or plead in this and the 75 other PPI cases filed on May 30 and 31, 2019. But, after conferring with his out-of-state lead counsel, Plaintiffs' Ohio counsel advised us that Plaintiffs would not agree to any extensions whatsoever.

In light of the foregoing, the Movants hereby move this Court for a 28-day extension to answer or otherwise plead in response to Plaintiff's voluminous complaint in this matter. A proposed order granting this Motion is being filed simultaneously.

Respectfully submitted,

ICE MILLER LLP

/s Daniel M. Anderson

Daniel M. Anderson (0067041)

Trial Attorney

250 West Street, Suite 700

Columbus, OH 43215

P: (614) 462-2700

F: (614) 462-5135

Daniel.Anderson@icemiller.com

Counsel for the Movants

OF COUNSEL:

Kristina Dahmann (0096414)

Lydia Reback (0097766)

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Columbus, Ohio 43215

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Fax: (614) 462-5135

Lydia.Reback@icemiller.com

Kristina.Dahmann@icemiller.com

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was filed electronically on July 1, 2019. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system and parties may access the filing through the Court's system.

/s/ Daniel M. Anderson

Daniel M. Anderson

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

This Document Relates To:

TERESA A. BEHYMER

29 Richmond Drive
Westchester, OH 45069

Plaintiff,

vs.

ABBOTT LABORATORIES

100 Abbott Park Road
Abbott Park, Illinois 60064

ASTRAZENECA PHARMACEUTICALS LP

1800 Concord Pike
Wilmington, Delaware 19850

ASTRAZENECA LP

1800 Concord Pike
Wilmington, Delaware 19850

**GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC**

184 Liberty Corner Road
Warren, New Jersey 07059

**MERCK & CO., INC. D/B/A MERCK, SHARP
& DOHME CORPORATION**

One Merck Drive
Whitehouse Station, New Jersey 08889

NOVARTIS CORPORATION

Lichtstrasse 35, CH-4056
Basel, Switzerland

**NOVARTIS PHARMACEUTICALS
CORPORATION**

One Health Plaza
East Hanover, New Jersey 07936

CASE NO: A 1902638

Judge

**ANSWER AND SEPARATE OR
AFFIRMATIVE DEFENSES OF
DEFENDANTS TAKEDA
PHARMACEUTICALS U.S.A., INC.,
TAKEDA PHARMACEUTICALS
AMERICA, INC., TAKEDA
DEVELOPMENT CENTER
AMERICAS, INC., formerly known
as TAKEDA GLOBAL RESEARCH
& DEVELOPMENT CENTER, INC.,
AND TAKEDA
PHARMACEUTICAL COMPANY
LIMITED**

**JURY DEMAND ENDORSED
HEREON**



VERIFY RECORD

**NOVARTIS INSTITUTES FOR
BIOMEDICAL RESEARCH, INC.**

250 Massachusetts Avenue
Cambridge, Massachusetts 02139

**NOVARTIS VACCINES AND
DIAGNOSTICS, INC.**

1 Health Plaza
East Hanover, New Jersey 07936

NOVARTIS CONSUMER HEALTH, INC.

200 Kimball Drive
Parsippany, New Jersey 07054

PFIZER, INC.

235 East 42nd Street
New York, New York 10017

THE PROCTER & GAMBLE COMPANY

1 Procter & Gamble Plaza
Cincinnati, Ohio 45202

**THE PROCTER & GAMBLE
MANUFACTURING COMPANY**

3875 Reservoir Road
Lima, Ohio 45801

TAKEDA PHARMACEUTICALS USA, INC.

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICALS AMERICA,
INC.**

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA DEVELOPMENT CENTER
AMERICAS, INC. F/K/A TAKEDA GLOBAL
RESEARCH & DEVELOPMENT CENTER,
INC.**

One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICAL COMPANY
LIMITED**

1-1, Doshomachi 4-chome Chuoku,

Osaka, Japan

Defendants.

COME NOW, Defendants Takeda Pharmaceuticals U.S.A., Inc. (“TPUSA”), Takeda Pharmaceuticals America, Inc. (“TPA”), Takeda Development Center Americas, Inc. (“TDC Americas”), formerly known as Takeda Global Research & Development Center, Inc., and Takeda Pharmaceutical Company Limited (“TPC”) (collectively, “Takeda”), by and through their attorneys, answer Plaintiff’s Complaint as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants’ defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys’ investigative efforts to date, regarding Defendants’ prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, “the PPI Products” or “PPIs”).

ANSWER: Takeda states that the allegations of this introductory paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. To the extent a response is required, Takeda admits that Plaintiff has brought personal injury actions against the named defendants, including Takeda, with respect to medications that they purport to define as “PPI Products.” Takeda also admits that TPC has designed, tested, developed, and manufactured Prevacid® and Dexilant®, (collectively, “Takeda Products”), TDCA has manufactured the Takeda Products, and TPA and TPUSA have manufactured, marketed and sold the Takeda Products. Takeda denies that it is liable to Plaintiff for any claims in any personal injury action and further denies any remaining allegations of Paragraph 1 that are directed to it.

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may

warrant.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies them.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

ANSWER: Takeda denies the allegations of paragraph 3.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. To the extent a response is required, Takeda admits that Plaintiff has brought a personal injury action against the named defendants, including Takeda, with respect to medications that Plaintiff purports to define as “PPI Products.” Takeda also admits that TPC has designed, tested, developed, and manufactured the Takeda Products, TDCA has manufactured the Takeda Products, and TPA and TPUSA have manufactured, marketed and sold the Takeda Products. Takeda denies that it is liable to Plaintiff for any claims in any personal injury action and further denies any remaining allegations of Paragraph 4 that are directed to it.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

ANSWER: Takeda admits that PPIs are indicated for the treatment of conditions such as:

Gastroesophageal reflux disease (“GERD”); dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers. Takeda also admits that the mechanism of action by which PPIs work is to inhibit the secretion of stomach acid by shutting down active acid pumps in the stomach, and that PPIs bind to proton pumps in the stomach, which inhibits secretion of gastric acid. Takeda denies any remaining or inconsistent allegations of paragraph 5.

PARTIES, JURISDICTION & VENUE

6. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court. The amount in controversy exceeds TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), exclusive of interest and costs, the jurisdictional minimum of this Court.

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda admits that Plaintiff purports to seek an amount in controversy that exceeds the jurisdictional limits of this Court. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6, and therefore denies them.

I. PLAINTIFF

7. Plaintiff, Teresa A. Behymer, resides in Westchester, Ohio and resided in Westchester, Ohio at all times relevant.

- a. Plaintiff, Teresa A. Behymer ingested the following PPI products sold by the Defendants from at least approximately January 2014 to December 2018: Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.
- b. As a direct and proximate result of Plaintiff’s use of the PPI(s), Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix, Plaintiff has suffered and was treated for, Chronic Kidney Disease (“CKD”) in approximately August 2016 with related sequelae.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff’s residence, use of Takeda Products, or medical conditions, and therefore denies them. Takeda admits that the Takeda Products are safe

and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 7 and specifically denies that Chronic Kidney Disease or Acute Kidney Injury was or is related to Takeda Products.

II. DEFENDANTS

8. Defendant Abbott Laboratories (“Defendant Abbott”) is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8, and therefore denies them.

9. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. Takeda admits that, at various times in the past, Abbott researched, tested, marketed, sold and distributed Prevacid®. Because the phrase “at all relevant times” is vague and ambiguous, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 9, and therefore denies them.

10. Defendant Abbott manufactures and markets Prevacid in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda denies the allegations of paragraph 10 on information and belief.

11. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11, and therefore denies them

12. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12, and therefore denies them.

13. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13, and therefore denies them.

14. Defendant AstraZeneca Pharmaceuticals LP (“AZ Pharm”) is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore denies them.

15. Defendant AstraZeneca LP (“AZ LP”) is, and at all times relevant to this action,

has been a limited partnership organized under the laws of Delaware having a principal place of business in Delaware, whose ultimate parent company is AstraZeneca PLC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore denies them.

16. Defendants AZ Pharm and AZ LP are referred to collectively herein as “AZ Defendants.”

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda admits that Plaintiff purports to refer to AZ Pharm and AZ LP as “AZ Defendants,” in their Complaint. Takeda denies any remaining allegations of paragraph 16.

17. Each of the AZ Defendants was the agent and employee of the other AZ Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other AZ Defendants’ actual and implied permission, consent, authorization and approval.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore denies them.

18. The AZ Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18, and therefore denies them.

19. As a part of their business and at all relevant times, the AZ Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19, and therefore denies them.

20. In 1982, the AZ Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20, and therefore denies them.

21. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21, and therefore denies them.

22. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec

which, by the year 2000, was the most widely prescribed drug in the world.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23, and therefore denies them.

24. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25, and therefore denies them.

26. In an agreement reached in December 1997, the AstraZeneca Defendants entered into a co-promotion agreement with the Procter & Gamble Defendants granting the Procter & Gamble Defendants the right to market Prilosec.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec and the Procter & Gamble Defendants market and sell Prilosec.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27, and therefore denies them.

28. Pursuant to the terms of the co-promotion agreement, the Procter & Gamble Defendants marketed and sold Prilosec from at least December 8, 1997 through January 12, 2001.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. In 2006, the FDA approved New Drug Application (“NDA”) 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29, and therefore denies them.

30. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30, and therefore denies them.

31. Defendant AZ LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31, and therefore denies them.

32. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 32, and therefore denies them.

33. In anticipation of the expiration of the patent for prescription Prilosec, the AZ Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 33, and therefore denies them.

34. In December 1999, Defendant AZ Pharm submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34, and therefore denies them.

35. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 35, and therefore denies them.

36. Defendant AZ Pharm is also the holder of approved NDAs 021957 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 36, and therefore denies them.

37. The AZ Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37, and therefore denies them.

38. In 2003, the AZ Defendants spent \$260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 38, and therefore denies them.

39. The AZ Defendants have transacted and conducted business related to PPI products in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 39, and therefore denies them.

40. The AZ Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was \$2.7 billion and world-wide was \$3.9 billion.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 40, and therefore denies them.

41. The AZ Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPIs.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 41, and therefore denies them.

42. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 42, and therefore denies them.

43. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, pursuant to an agreement with the Novartis Defendants, obtained the rights to market and sell the over-the-counter medication Prevacid 24Hr.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda admits, on information and belief, that GlaxoSmithKline Consumer Healthcare Holdings (US) obtained the rights to market and sell Prevacid 24HR® in 2014. Takeda states that Plaintiff's grouping of multiple entities into the term "Novartis Defendants" renders the remaining allegations of this paragraph vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 43, and therefore denies them.

44. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, in collaboration and amongst themselves, designed and developed Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 44, and therefore denies them.

45. As a part of their business and at all relevant times, Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 45, and therefore denies them.

46. Defendant GSK Consumer Healthcare (US) IP LLC is the holder of approved NDA 022327 for Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda admits that GlaxoSmithKline Consumer Health Care is the holder of approved NDA 022327. Takeda denies any remaining or inconsistent allegations of paragraph 46.

47. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC manufacture and market Prevacid 24HR in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda admits, on information and belief, that GlaxoSmithKline Consumer Health Care Holdings (US) markets Prevacid 24HR® in the United States. Takeda lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations of paragraph 47, and therefore denies them.

48. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 48, and therefore denies them.

49. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations

as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 49, and therefore denies them.

50. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 50 and therefore denies them.

51. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter “Defendant Merck”) is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51, and therefore denies them.

52. In 1982, Defendant Merck entered into an agreement with the AZ Defendants, under the terms of which Defendant Merck developed and marketed the AZ Defendants’ products, including Nexium and Prilosec products, under a royalty-bearing license.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 52, and therefore denies them.

53. In 1993, Merck’s total sales of the AstraZeneca Defendants’ products reached a level that triggered the first step in the establishment of a joint venture business (the “Joint Venture”) in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share.

This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 53, and therefore denies them.

54. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 54, and therefore denies them.

55. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 55, and therefore denies them.

56. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 56, and therefore denies them.

57. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 57, and therefore denies them.

58. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 58, and therefore denies them.

59. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 59, and therefore denies them.

60. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 60, and therefore denies them.

61. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 61, and therefore denies them.

62. Defendant Merck manufactures and markets Nexium products in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 62, and therefore denies them.

63. Defendant Merck manufactures and markets Prilosec products in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 63, and therefore denies them.

64. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 64, and therefore denies them.

65. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 65, and therefore denies them.

66. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 66, and therefore denies them.

67. Defendant Novartis Corporation is and, at all times relevant to this action, has been a New York corporation having a principal place of business in East Hanover, NJ.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 67, and therefore denies them.

68. Defendant Novartis Pharmaceuticals Corporation is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, NJ 07936.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 68, and therefore denies them.

69. Defendant Novartis Institutes for Biomedical Research, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business at 250 Massachusetts Avenue, Cambridge, MA 02139.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69, and therefore denies them.

70. Defendant Novartis Vaccines and Diagnostics, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business in East Hanover, NJ.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70, and therefore denies them.

71. Defendant Novartis Corporation is the parent/holding company of Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 71, and therefore denies them.

72. At all relevant times, Defendant Novartis Corporation has exercised and exercises dominion and control over Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 72, and therefore denies them.

73. Defendants Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc. are herein referred to collectively as “Novartis Defendants.”

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda admits that Plaintiff purports to refer to Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc. as “Novartis Defendants” in their Complaint. Takeda denies any remaining allegations of paragraph 73.

74. Each of the Novartis Defendants was the agent and employee of the other Novartis Defendants, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Novartis Defendants’ actual and implied permission, consent, authorization and approval.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 74, and therefore denies them.

75. In 2005, the Novartis Defendants obtained the rights to market the over-the-counter version of Prevacid, Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda admits that, in December 2005, Novartis AG acquired the rights to market Prevacid 24HR® from TAP Pharmaceuticals, Inc. Takeda denies any remaining or inconsistent allegations of paragraph 75.

76. As part of their business and at all relevant times, the Novartis Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing,

sale and distribution of Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda states that Plaintiff's grouping of multiple entities into the term "Novartis Defendants" and use of the phrase "at all relevant times" renders the allegations in this paragraph vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 76, and therefore denies them.

77. The Novartis Defendants, in collaboration amongst themselves, designed and developed the Prevacid 24 HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda states that Plaintiff's grouping of multiple entities into the term "Novartis Defendants" renders the allegations of this paragraph vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 77, and therefore denies them.

78. Defendant Novartis Pharmaceuticals Corporation has been the holder of approved NDA 022327 for Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 78, and therefore denies them.

79. The Novartis Defendants manufacture and market Prevacid 24HR in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda

admits, on information and belief, that GlaxoSmithKline Consumer Health Care Holdings (US) markets Prevacid 24HR® in the United States. Takeda states that Plaintiff's grouping of multiple entities into the term "Novartis Defendants" renders the remaining allegations in this paragraph vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 79, and therefore denies them.

80. The Novartis Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 80, and therefore denies them.

81. The Novartis Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 81, and therefore denies them.

82. The Novartis Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 82, and therefore denies them.

83. Defendant Pfizer Inc. is and, all times relevant to this action, has been a Delaware

corporation having a principal place of business at 235 East 42nd Street, New York, NY 10017.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 83, and therefore denies them.

84. As a part of their business and at all relevant times, Defendant Pfizer Inc. has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of the drugs Protonix (pantoprazole) and Nexium 24HR.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 84, and therefore denies them.

85. In or about 2012, Defendant Pfizer Inc. entered into a marketing agreement with the AstraZeneca Defendants whereby Defendant Pfizer Inc. acquired the rights to market Nexium 24HR products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 85, and therefore denies them.

86. On or about March 28, 2014, Defendant Pfizer Inc., in collaboration with and pursuant to its marketing agreement with the AstraZeneca Defendants, was granted FDA approval to market Nexium 24HR products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks

knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 86, and therefore denies them.

87. Defendant Pfizer Inc. makes Nexium 24HR available for purchase in the United States in and around 2014 and continues to manufacture and market Nexium 24HR in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 87, and therefore denies them.

88. Defendant Pfizer Inc. manufactures and markets Protonix in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 88, and therefore denies them.

89. Defendant Pfizer Inc. has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 89, and therefore denies them.

90. Defendant Pfizer Inc. has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 90, and therefore denies them.

91. Defendant Pfizer Inc. has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 91, and therefore denies them.

92. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 92, and therefore denies them.

93. Defendant The Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 93, and therefore denies them.

94. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests of Defendant The Procter & Gamble Manufacturing Company.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations

as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 94, and therefore denies them.

95. Defendant The Procter & Gamble Company and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no response by Takeda is required. If a response is required, Takeda admits that Plaintiff purports to refer to The Procter & Gamble Company and Procter & Gamble Manufacturing Company collectively as “the Procter & Gamble Defendants” in this Complaint. Takeda denies any remaining allegations in paragraph 95.

96. Each of the Procter & Gamble Defendants was the agent and employee of the Other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant’s actual and implied permission, consent, authorization and approval.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96, and therefore denies them.

97. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 97, and therefore denies them.

98. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 98, and therefore denies them.

99. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 99, and therefore denies them.

100. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 100, and therefore denies them.

101. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 101, and therefore denies them.

102. The Procter & Gamble Defendants made Prilosec OTC available for purchase in

the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 102, and therefore denies them.

103. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 103, and therefore denies them.

104. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 104, and therefore denies them.

105. The Procter & Gamble Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prilosec OTC.

ANSWER: Takeda states that the allegations of this paragraph do not state any allegations as to Takeda and, therefore, no answer by Takeda is required. If an answer is required, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 105, and therefore denies them.

106. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Takeda admits that TPUSA is a Delaware corporation with its principal place of business at One Takeda Parkway in Deerfield, Illinois. Takeda denies the remaining allegations of paragraph 106.

107. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Takeda admits that TPA is a Delaware corporation with its principal place of business at One Takeda Parkway in Deerfield, Illinois. Takeda denies the remaining allegations of paragraph 107.

108. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

ANSWER: Takeda denies the allegations of Paragraph 108, and states that TPLLC was wholly-owned by TPUSA before its dissolution. Takeda denies any remaining allegations of paragraph 108.

109. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: Takeda admits that TDC Americas is a Delaware corporation with its principal place of business at One Takeda Parkway in Deerfield, Illinois. Takeda denies the remaining allegations of paragraph 109.

110. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

ANSWER: Takeda admits that TPC is a Japanese corporation with its principal place of

business at 1-1, Doshomachi 4-chome, Chuoku in Osaka, Japan. Takeda denies any remaining allegations of paragraph 110.

111. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Takeda admits that TPC is a parent company of TPUSA, TPA, and TDC Americas. Takeda denies any remaining allegations of paragraph 111.

112. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Takeda states that the phrases “at all relevant times,” “exercised and exercises,” and “dominion and control” are vague and ambiguous. Accordingly, Takeda denies them. Takeda denies any remaining or inconsistent allegations of paragraph 112.

113. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

ANSWER: Takeda states that the allegations of this paragraph do not require a response. If a response is required, Takeda admits that Plaintiff refers to TPUSA, TPA, and TDC Americas, as “Takeda Defendants.” Takeda denies any remaining allegations of paragraph 113.

114. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

ANSWER: Takeda denies the allegations of paragraph 114.

115. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of, Prevacid, Prevacid 24HR and Protonix products.

ANSWER: Takeda states that the phrase “at all relevant times” is vague and ambiguous and that Plaintiff’s grouping of multiple entities into the term “Takeda Defendants” further renders the allegations vague and ambiguous. Accordingly, Takeda denies them. Takeda admits that TPC has been involved in the design, research, testing, development, and manufacturing of the Takeda Products, TDC Americas has be involved in the manufacturing of the Takeda Products, and TPA and TPUSA have been involved in the manufacturing, marketing, and sale of the Takeda Products. Takeda denies the remaining allegations of paragraph 115.

116. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid, Prevacid 24HR, and Protonix products.

ANSWER: Takeda states that Plaintiff’s grouping of multiple entities into the term “Takeda Defendants” renders the allegations in paragraph 116 vague and ambiguous. Accordingly, Takeda denies them. Takeda admits that TPC was involved in the design and development of the Takeda Products. Takeda denies the remaining allegations of paragraph 116.

117. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

ANSWER: Takeda admits that TPUSA is the holder of approved New Drug Applications (“NDAs”) 020406, 021428, and 021281. Takeda denies any remaining allegations of paragraph 117.

118. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

ANSWER: Takeda states that Plaintiff’s grouping of multiple entities into the term “Takeda Defendants” renders the allegations in paragraph 118 vague and ambiguous. Accordingly, Takeda denies them. Takeda admits that TPC has manufactured Prevacid®, that TDC Americas has be involved in the manufacturing of Prevacid®, and that TPA and TPUSA have marketed Prevacid® in the United States. Takeda denies the remaining allegations of

paragraph 118.

119. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

ANSWER: Takeda denies the allegations of paragraph 119.

120. The Takeda Defendants manufacture and market each of these Protonix formulations in the United States.

ANSWER: Takeda denies the allegations of paragraph 120.

121. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda states that Plaintiff's grouping of multiple entities into the term "Takeda Defendants" renders the allegations in paragraph 121 vague and ambiguous. Accordingly, Takeda denies them. Takeda admits that TPC has been involved in the design, research, testing, development, and manufacturing of the Takeda Products, TDC Americas has been involved in the manufacturing of the Takeda Products, and TPA and TPUSA have been involved in the manufacturing, marketing, and sale of the Takeda Products. Takeda denies the remaining allegations of paragraph 121.

122. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: Takeda admits that it has received revenue from the sale of the Takeda Products and from the sale of certain PPI products in the United States. Takeda states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Takeda denies any remaining or inconsistent allegations of paragraph 122.

123. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial

revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: Takeda states that the phrases “their acts,” “consequence,” and “substantial revenue” are vague and ambiguous. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Takeda denies the remaining allegations of paragraph 123.

124. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no answer is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda admits that TPUSA and TPA have engaged in the business of marketing pharmaceutical products in the United States, including the Takeda Products at issue in this personal injury litigation. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 124 at this time, and therefore denies them. Takeda reserves the right to contest personal jurisdiction, as appropriate, in individual cases.

125. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no answer is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda admits that TPUSA and TPA have engaged in the business of marketing pharmaceutical products in the United States. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 125. Takeda reserves the right to contest personal jurisdiction, as appropriate, in

individual cases.

FACTUAL ALLEGATIONS

126. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

ANSWER: Takeda admits that PPIs are indicated for the treatment of conditions such as: Gastroesophageal reflux disease (“GERD”); dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers. Takeda denies any remaining allegations of paragraph 126.

127. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

ANSWER: Takeda admits that the mechanism of action by which PPIs work is to inhibit the secretion of stomach acid by shutting down active acid pumps in the stomach. Takeda also admits that PPIs bind to proton pumps in the stomach, which inhibits secretion of gastric acid. Takeda denies any remaining or inconsistent allegations of paragraph 127.

128. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

ANSWER: Takeda states that the allegations of this paragraph are vague and ambiguous as written. As such, Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 128, and therefore denies them.

129. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs’ global sales and earning an estimated \$11 billion annually.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 129, and therefore denies them.

130. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 130, and therefore denies them.

131. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 131, and therefore denies them.

132. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

ANSWER: Takeda admits that Dr. Stephen Ruffenach and other researchers from the University of Arizona Health Sciences Center published an article in the American Journal of Medicine in 1992 and states that the article speaks for itself. Takeda denies any remaining or inconsistent allegations of paragraph 132.

133. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

ANSWER: Takeda states that the allegations of paragraph 133 are vague and ambiguous. Therefore, Takeda lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

134. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

ANSWER: Takeda states that the allegations of paragraph 134 are vague and ambiguous. Therefore, Takeda lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

135. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

ANSWER: Takeda admits that researchers from the Yale School of Medicine published an article in the International Society of Nephrology's Kidney International in 2006 and states that the article speaks for itself. Takeda denies any remaining or inconsistent allegations of paragraph 135.

136. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

ANSWER: Takeda admits that Dr. F. Sierra and others published an article in the Journal of Alimentary Pharmacology and Therapeutics in 2007 and states that the article speaks for itself. Takeda denies any remaining or inconsistent allegations of paragraph 136.

137. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, "where PPI-induced AIN is disproportionately present in the database." Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

ANSWER: Takeda states that Dr. Harmark and others published an article in the British Journal of Clinical Pharmacology in 2007 and states that the article speaks for itself. Takeda denies any remaining or inconsistent allegations of paragraph 137.

138. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

ANSWER: Takeda admits that on August 23, 2011, Public Citizen filed a petition with the FDA requesting that additional warnings be added to the labeling of PPI products. Takeda denies the validity of this citizen's petition and further denies the remaining allegations of

paragraph 138.

139. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

ANSWER: Takeda admits that the Public Citizen petition filed with the FDA on August 23, 2011 stated that “[i]nformation regarding the potential for drug-induced acute interstitial nephritis, seen in at least 60 case reports, should be included in the appropriate section. There is currently no detailed risk information on any PPI for this adverse effect.” Takeda denies the validity of this citizen’s petition and further denies the remaining allegations of paragraph 139.

140. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

ANSWER: Takeda admits that on October 31, 2014, the FDA responded to Public Citizen’s petition by concluding that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Takeda denies the remaining allegations of paragraph 140.

141. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

ANSWER: Takeda admits that on October 31, 2014, the FDA stated:

Although nearly all prescription PPI products mention the risk of AIN in their labeling, those warnings do not currently appear class-wide and vary to some extent between products. Because we agree that the prescription PPI labeling should be consistent with regard to this risk and because there is reasonable evidence of a causal association, your Petition is granted with respect to this request, and we are working with sponsors of prescription PPI products to make this information consistent with product labeling throughout the class.

Takeda denies the remaining allegations of paragraph 141.

142. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

ANSWER: Takeda admits that in December 2014 the labeling for Prevacid® and Dexilant® was updated to include the statement quoted in this allegation. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 142, and therefore denies them.

143. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

ANSWER: Takeda states that the allegations of this paragraph are vague and ambiguous, especially as to the identification of the products at issue in this paragraph. Accordingly, Takeda lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them. Takeda specifically denies that it markets any "over-the-counter PPI Products" as alleged in paragraph 143.

144. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

ANSWER: Takeda denies the allegations of paragraph 144.

145. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the-counter PPI Products.

ANSWER: Takeda denies the allegations of paragraph 145.

146. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

ANSWER: Takeda denies that that the mechanism by which drugs may cause AIN has been established. Takeda denies any remaining or inconsistent allegations of paragraph 146.

147. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

ANSWER: Takeda admits that not every patient diagnosed with AIN presents with a fever. Takeda denies any remaining or inconsistent allegations of paragraph 147.

148. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

ANSWER: Takeda admits that the publications referenced in this paragraph are in the published literature and state that these publications speak for themselves. Takeda denies that the mechanism by which drugs may cause AIN has been established and further denies any remaining or inconsistent allegations of paragraph 148.

149. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

ANSWER: Takeda states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Takeda lacks knowledge or information sufficient to form a belief as to the truth the remaining allegations of paragraph 149, and therefore denies them.

150. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

ANSWER: Takeda states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Takeda denies that the Takeda Products cause chronic kidney disease or end stage renal failure. Takeda lacks knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 150, and

therefore denies them.

151. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ANSWER: Takeda states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Takeda denies that the Takeda Products cause chronic kidney disease. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 151, and therefore denies them.

152. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

ANSWER: Takeda denies that the Takeda Products cause acute kidney injury or renal failure. Takeda lacks knowledge or information sufficient to form a belief as to the truth, of the remaining allegations of paragraph 152, and therefore denies them.

153. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

ANSWER: Takeda states that the term “studies” is vague and ambiguous. Therefore, Takeda lacks knowledge or information sufficient to form a belief as to their truth, and denies them. Takeda denies that the Takeda Products cause acute kidney injury and further denies any remaining allegations of paragraph 153.

154. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

ANSWER: Takeda states that the term “studies” is vague and ambiguous. Therefore, Takeda lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them. Takeda states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Takeda denies any remaining allegations of paragraph 154.

155. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

ANSWER: Takeda admits that the current Takeda Products' product labeling does not explicitly reference AKI as defined in the Plaintiff's Complaint. Takeda further admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that the Takeda Products cause or increase the risk of kidney injury, and further denies any remaining or inconsistent allegations of paragraph 155.

156. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

ANSWER: Takeda admits that chronic kidney disease is the gradual loss of kidney function. Takeda denies that the Takeda Products cause chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 156.

157. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

ANSWER: Takeda admits that chronic kidney disease is the gradual loss of kidney function. Takeda denies that the Takeda Products cause chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 157.

158. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

ANSWER: Takeda admits that chronic kidney disease can, but does not always, lead to the development of end stage renal disease. Takeda denies that the Takeda Products cause chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 158.

159. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

ANSWER: Takeda admits that a study was published in the Journal of the American Medical Association in January 2016 which referenced use of PPI products. Takeda states that this study speaks for itself. Takeda denies that the Takeda Products cause chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 159.

160. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

ANSWER: Takeda admits that a study was published in the Journal of the American Society of Nephrology in February 2016 which referenced use of PPI products. Takeda states that this study speaks for itself. Takeda denies that the Takeda Products cause chronic kidney disease, progression of kidney disease, or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 160.

161. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

ANSWER: Takeda admits that a study was published in the Journal of Nephrology in April 2016 which referenced use of PPI products. Takeda states that this study speaks for itself. Takeda denies that the Takeda Products cause chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 161.

162. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

ANSWER: Takeda denies the allegations characterizing chronic kidney disease in

paragraph 162 and further denies that the Takeda Products cause chronic kidney disease or end stage renal failure. Takeda denies any remaining allegations of paragraph 162.

163. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int’l 1482 (2017).

ANSWER: Takeda admits that a study was published in the Kidney International in 2017, which referenced use of PPI products. Takeda states that this study speaks for itself. Takeda denies that the Takeda Products cause chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 163.

164. To date, the labeling for Defendants’ PPI Products lack adequate risk information about CKD.

ANSWER: Takeda denies the allegations of paragraph 164.

165. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

ANSWER: Takeda denies the allegations of paragraph 165.

166. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 166.

167. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

ANSWER: Takeda states that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda lacks knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of paragraph 167, and therefore denies them.

168. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases beyond their pre-PPI treatment levels.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 168.

169. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 169.

170. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 170.

171. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 171.

172. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 172.

173. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

ANSWER: Takeda denies the allegations of paragraph 173.

174. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as "H₂ Blockers") that were developed in the late 1960s. H₂ Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H₂ Blockers include Zantac, Pepcid and Tagamet. H₂ Blockers are not associated with an increased risk of kidney injuries.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 174.

175. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies any remaining or inconsistent allegations of paragraph 175.

176. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and

have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 176.

177. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 177.

178. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

ANSWER: Takeda denies the allegations of paragraph 178.

179. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Takeda Products or Plaintiff's medical conditions, and therefore denies them. Takeda denies any remaining allegations of paragraph 179.

180. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Takeda Products or Plaintiff's

medical conditions, and therefore denies them. Takeda denies any remaining allegations of paragraph 180.

181. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

ANSWER: Takeda denies the allegations of paragraph 181.

182. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

ANSWER: Takeda denies the allegations of paragraph 182.

183. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 183.

184. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

ANSWER: Takeda denies the allegations of paragraph 184.

185. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 185.

186. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no answer is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies any remaining allegations of paragraph 186.

187. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no answer is required. To the extent that the allegations are construed as factual allegations directed to Takeda, Takeda admits that, pursuant to approval by the FDA, TPUSA and TPA have marketed the Takeda Products in the United States, including in direct to consumer advertisements. Takeda denies any remaining allegations of paragraph 187.

188. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

ANSWER: To the extent that the allegations of paragraph 188 are directed to Takeda, Takeda denies them.

189. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

ANSWER: To the extent that the allegations of paragraph 189 are directed to Takeda, Takeda denies them.

190. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

ANSWER: To the extent that the allegations of paragraph 190 are directed to Takeda,

Takeda denies them.

191. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

ANSWER: Takeda denies the allegations of paragraph 191.

192. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that additional labeling was or is warranted for the Takeda Products, and further denies any remaining or inconsistent allegations of paragraph 192.

193. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

ANSWER: To the extent that the allegations of paragraph 193 are directed to Takeda, Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that additional labeling was or is warranted for the Takeda products, and further denies any remaining allegations of paragraph 193.

194. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

ANSWER: To the extent that the allegations of paragraph 194 are directed to Takeda, Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that additional labeling was or is warranted for the Takeda Products, and further denies any remaining allegations of paragraph 194.

195. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

ANSWER: To the extent that the allegations of paragraph 195 are directed to Takeda, Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that additional labeling was or is warranted for the Takeda Products, and further denies any remaining allegations of paragraph 195.

196. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

ANSWER: To the extent that the allegations of paragraph 196 are directed to Takeda, Takeda denies them.

197. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;
- d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
- e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;
- f. Defendants violated 21 CFR § 201.56 because the labeling of their respective

- prescription PPI Products were and are not informative and accurate;
- g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;
 - h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;
 - i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;
 - j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR § 201.66 because they were and are not informative and accurate;
 - k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR § 201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;
 - l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;
 - m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;
 - n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;
 - o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;
 - p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;
 - q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;
 - r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;
 - s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drugs experience report;
 - t. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

- u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;
- v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;
- w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;
- x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;
- y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and
- z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.
- aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ANSWER: Takeda states that the allegations of paragraph 197 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Takeda, Takeda denies them, including all subparts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as

if fully set forth herein.

199. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

ANSWER: Takeda states that the allegations of paragraph 199 constitute legal conclusions to which no response is required. If the allegations of paragraph 199 are construed as factual allegations directed to Takeda, Takeda admits that Plaintiff purports to assert tolling of relevant statutes of limitations, but denies that Plaintiff is entitled to such tolling. Takeda denies any remaining allegations of paragraph 199.

200. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

ANSWER: Takeda states that the allegations of paragraph 200 constitute legal conclusions to which no response is required. If the allegations of paragraph 200 are construed as factual allegations directed to Takeda, Takeda admits that Plaintiff purports to assert application of the discovery rule, but denies that Plaintiff is entitled to such application. Takeda denies any remaining allegations of paragraph 200.

201. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

ANSWER: Takeda states that the allegations of paragraph 201 constitute legal conclusions to which no response is required. If the allegations of paragraph 201 are construed as factual allegations directed to Takeda, Takeda denies them.

202. The running of the statute of limitations in this case is tolled due to equitable tolling.

Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

ANSWER: Takeda states that the allegations of paragraph 202 constitute legal conclusions to which no response is required. If the allegations of paragraph 202 are construed as factual allegations directed to Takeda, Takeda denies them.

203. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies any remaining allegations of paragraph 203.

204. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

ANSWER: To the extent that the allegations of paragraph 204 are directed to Takeda, Takeda denies them.

205. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

ANSWER: To the extent that the allegations of paragraph 205 are directed to Takeda, Takeda denies them.

206. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

ANSWER: To the extent that the allegations of paragraph 206 are directed to Takeda, Takeda denies them.

207. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 207 regarding Plaintiff's use of PPI products and regarding Plaintiff's medical conditions, and therefore denies them. Takeda denies any remaining allegations of paragraph 207.

208. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 208 regarding Plaintiff's use of PPI products or medical conditions, and therefore denies them. Takeda denies any remaining allegations of paragraph 208.

209. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 209 regarding Plaintiff's medical condition, and therefore denies them. Takeda denies any remaining allegations of paragraph 209.

210. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and

wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

ANSWER: To the extent the allegations of paragraph 210 are directed to Takeda, Takeda denies them.

211. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 211 regarding Plaintiff's use of PPI products or medical condition, and therefore denies them. Takeda denies any remaining allegations of paragraph 211.

CAUSES OF ACTION

COUNT I **STRICT PRODUCT LIABILITY**

212. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

213. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 213 and specifically denies that the Takeda Products were defective or unreasonably dangerous.

214. At the time of the Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 214 and specifically denies that the Takeda Products were defective or unreasonably dangerous.

215. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

ANSWER: Takeda admits that, pursuant to FDA approval, TPC has been involved in designing, researching, and manufacturing the Takeda Products, TDC Americas has been involved in the manufacturing of the Takeda Products, and TPA and TPUSA have been involved in the manufacturing, marketing and sale of the Takeda Products in the United States. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of the Takeda Products, and therefore denies them. Takeda denies the remaining allegations of paragraph 215.

216. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

ANSWER: Takeda admits that the Takeda Products were expected to reach intended consumers without substantial change in the condition in which they were sold. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that the Takeda Products "did reach" users without substantial change in the condition in which they were sold, and therefore denies them. Takeda denies the remaining allegations of paragraph 216.

217. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including the Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when

prescribed and used in accordance with their FDA-approved labeling. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Takeda Products, and therefore denies them. Takeda denies the remaining allegations of paragraph 217, and specifically denies that the Takeda Products are or were manufactured in an unsafe, defective or inherently dangerous condition.

218. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 218, and specifically denies that the Takeda Products are or were defective.

219. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 219, and specifically denies that the Takeda Products are or were defective or unsafe.

220. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining

allegations of paragraph 220, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous.

221. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 221, and specifically denies that the Takeda Products are or were defective, inherently dangerous, or unsafe.

222. At the time, the Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 222, and therefore denies them.

223. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 223.

224. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, it admits that it complied with its duty under the law at all times. Takeda denies any remaining or inconsistent allegations of paragraph 224.

225. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

ANSWER: Takeda denies the allegations of paragraph 225.

226. The PPI Products designed, researched, manufactured, tested, advertised,

promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 226, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous.

227. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 227, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous.

228. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 228.

229. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 229, and specifically denies that the Takeda Products are or were defective or dangerous.

230. The PPI Products designed, researched, manufactured, tested, advertised,

promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 230, and specifically denies that the Takeda Products are or were defective and that they cause kidney or other injuries.

231. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 231, and specifically denies that the Takeda Products are or were defective or dangerous.

232. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 232, and specifically denies that the Takeda Products are or were defective or dangerous.

233. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 233, and specifically denies that the Takeda Products are or were defective.

234. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 234, and specifically denies that the Takeda Products are or were defective.

235. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 235, and therefore denies them.

236. Plaintiff did not misuse or materially alter the PPI Products.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 236, and therefore denies them.

237. Defendants are strictly liable for the Plaintiff's injuries in the following ways:
- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
 - b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
 - c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
 - d. Defendants failed to adequately test their PPI Products;

- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 237, including all subparts, and specifically denies that the Takeda Products are or were defective or dangerous.

238. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

ANSWER: Takeda denies the allegations of paragraph 238.

239. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Takeda denies the allegations of paragraph 239.

240. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

ANSWER: Takeda denies the allegations of paragraph 240.

241. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies the allegations of paragraph 241.

242. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, the Plaintiff, and/or the Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 242.

WHEREFORE, the Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

243. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. The Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

244. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 244, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous.

245. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 245.

246. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary

consumer would have expected.

ANSWER: Takeda denies the allegations of paragraph 246.

247. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 247, and therefore denies them.

248. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

ANSWER: Takeda denies the allegations of paragraph 248.

249. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

ANSWER: Takeda admits that Takeda Products were expected to reach intended consumers without substantial change in the condition in which they were sold. Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that the Takeda Products "did reach" intended consumers, including Plaintiff, without substantial change in the condition in which they were sold, and therefore denies them. Takeda denies any remaining allegations of paragraph 249.

250. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

ANSWER: Takeda denies the allegations of paragraph 250.

251. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

ANSWER: Takeda denies the allegations of paragraph 251, and specifically denies that the Takeda Products are or were defective or dangerous.

252. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 252, and specifically denies that the Takeda Products are or were defective or unsafe.

253. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 253.

254. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 254.

255. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiff specifically were not aware of these risks, nor would they expect such risks.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 255.

256. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with the design or formulation of the PPI Products, as defined by Ohio Rev. Code. §§ 2307.75(C), or

they were more dangerous than an ordinary consumer would expect.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 256.

257. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, as defined at Ohio Rev. Code. §§ 2307.75(B)(1)-(5), include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury, as defined at Ohio Rev. Code §§ 2307.75(B)(4), specifically, the risk of kidney injuries.
- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 257, including all subparts.

258. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining

allegations of paragraph 258.

259. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 259.

260. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 260.

261. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 261.

262. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 262.

263. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 263.

264. The unreasonably dangerous nature of Defendants' PPI Products caused serious

harm to Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 264 and specifically denies that the Takeda Products are or were unreasonably dangerous.

265. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

ANSWER: Takeda denies the allegations of paragraph 265 and specifically denies that the Takeda Products are or were dangerous.

266. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

ANSWER: Takeda denies the allegations of paragraph 266 and specifically denies that the Takeda Products are or were dangerous.

267. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 267 and specifically denies that the Takeda Products are or were defective or unsafe.

268. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 268.

269. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further

denies the remaining allegations of paragraph 269.

270. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 270.

271. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Takeda denies the allegations of paragraph 271.

272. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 272.

273. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

ANSWER: Takeda denies the allegations of paragraph 273.

274. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff's injuries and damages.

ANSWER: Takeda denies the allegations of paragraph 274.

275. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 275 and specifically denies that Takeda Products are

defective in design or formulation, or unsafe.

276. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: Takeda denies the allegations of paragraph 276.

277. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

ANSWER: Takeda denies the allegations of paragraph 277.

278. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Takeda denies the allegations of paragraph 278.

279. The defective nature of the PPI Products was a substantial factor in causing Plaintiff's injuries.

ANSWER: Takeda denies the allegations of paragraph 279 and specifically denies that the Takeda Products were or are defective.

280. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies the allegations of paragraph 280.

281. Defendants' conduct, as described herein, was extreme and outrageous.

ANSWER: Takeda denies the allegations of paragraph 281.

282. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming

public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 282.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

284. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

ANSWER: Takeda admits that, pursuant to FDA approval, TPC, TDC Americas, TPUSA, and TPA have been involved in manufacturing the Takeda Products and TPA and TPUSA have been involved in the distribution and sale of the Takeda Products in the United States. Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 284, and specifically denies that the Takeda Products are or were dangerous or cause kidney or other personal injuries.

285. In addition to, or in the alternative, the PPI Products manufactured and supplied by

Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 285, and specifically denies that the Takeda Products are or were defective.

286. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, it admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 286.

287. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 287.

288. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 288.

289. The risks of PPI Products were not open and obvious, as defined at Ohio Rev. Code Code §§ 2307.76(B).

ANSWER: Takeda states that the allegations of paragraph 289 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 289.

290. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

ANSWER: Takeda denies the allegations of paragraph 290.

291. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Takeda denies the allegations of paragraph 291.

292. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, denies that the Takeda Products are or were defective or unreasonably dangerous, and further denies the remaining allegations of paragraph 292.

293. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 293, and specifically denies the Takeda Products are or were defective or unreasonably dangerous.

294. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 294, and therefore denies them.

295. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

ANSWER: Takeda denies the allegations of paragraph 295, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous. Takeda denies the remaining allegations of paragraph 295, and specifically denies that the Takeda Products are or were defective or unreasonably dangerous.

296. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

ANSWER: Takeda states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 296.

297. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

ANSWER: Takeda denies the allegations of paragraph 297.

298. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

ANSWER: Takeda denies the allegations of paragraph 298.

299. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, it admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 299.

300. Had Plaintiff and/or her healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

ANSWER: Takeda denies the allegations of paragraph 300.

301. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

ANSWER: Takeda denies the allegations of paragraph 301.

302. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 302.

303. Plaintiff and her healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 303.

304. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

ANSWER: Takeda denies the allegations of paragraph 304.

305. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

ANSWER: Takeda denies the allegations of paragraph 305.

306. Plaintiff's healthcare providers reasonably relied upon the representations, warning

and instructions provided by Defendants for use and administration of their PPI Products.

ANSWER: Takeda denies the allegations of paragraph 306.

307. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the allegations of paragraph 307.

308. Defendants' conduct as described herein was a substantial factor in causing Plaintiff's injuries.

ANSWER: Takeda denies the allegations of paragraph 308.

309. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: Takeda denies the allegations of paragraph 309.

310. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 310.

311. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

ANSWER: Takeda denies the allegations of paragraph 311.

312. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 312.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT IV **NEGLIGENCE**

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

314. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, it admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 314.

315. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs

could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

ANSWER: Takeda denies the allegations of paragraph 315.

316. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
- k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
- m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use

- of their PPI Products;
- n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
- o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
- p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
- q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
- r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
- s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
- t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
- v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
- w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
- x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
- y. Failing to use due care under the circumstances; and
- z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that the Takeda Products cause kidney or other injuries and further denies the remaining allegations of paragraph 316, including all subparts.

317. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 317.

318. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

ANSWER: Takeda denies the allegations of paragraph 318.

319. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 319.

320. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 320.

321. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ANSWER: Takeda denies the allegations of paragraph 321.

322. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

ANSWER: Takeda denies the allegations of paragraph 322.

323. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Takeda denies the allegations of paragraph 323.

324. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

ANSWER: Takeda denies the allegations of paragraph 324.

325. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies the allegations of paragraph 325.

326. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 326.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT V
NEGLIGENCE PER SE

327. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

328. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et

seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

ANSWER: Takeda states that the allegations of paragraph 328 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Takeda, Takeda denies them.

329. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

ANSWER: Takeda states that the allegations of paragraph 329 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda denies them.

330. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

ANSWER: Takeda denies the allegations of paragraph 330.

331. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

ANSWER: Takeda states that the allegations of paragraph 331 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda denies them.

332. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

ANSWER: Takeda states that the allegations of paragraph 332 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Takeda, Takeda denies them.

333. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished

enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 333.

334. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 334.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

336. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty

under the law at all times. Takeda further admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 336, and specifically denies that the Takeda Products were unreasonably dangerous.

337. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 337.

338. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 338.

339. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

ANSWER: Takeda denies the allegations of paragraph 339.

340. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 340.

341. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

ANSWER: Takeda denies the allegations of paragraph 341.

342. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure caused by the use of the PPI Products.

ANSWER: Takeda denies the allegations of paragraph 342.

343. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

ANSWER: Takeda denies the allegations of paragraph 343.

344. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

ANSWER: Takeda denies the allegations of paragraph 344.

345. Defendants are strictly liable for the Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

ANSWER: Takeda denies the allegations of paragraph 345.

346. As a direct and proximate result of Defendants' wrongful actions and failure to test, the Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 346.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

347. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

348. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of PPI Products and made representations regarding the character or quality of PPI Products including but not limited to the fact that PPI Products were safe and effective in its ordinary use.

ANSWER: Takeda admits that TPC has designed, developed, and manufactured the Takeda Products, TDC Americas has manufactured the Takeda Products, and TPUSA and Takeda TPA have manufactured, marketed and sold the Takeda Products. Takeda further admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 348.

349. The PPI Products manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

ANSWER: Takeda denies the allegations of paragraph 349, and specifically denies that the Takeda Products are or were defective.

350. These material misrepresentations made by the Defendants were false.

ANSWER: Takeda denies the allegations of paragraph 350.

351. Plaintiff justifiably relied upon Defendants' representations regarding PPI Products.

ANSWER: Takeda denies the allegations of paragraph 351.

352. Upon information and belief, the warnings provided to those who chose to use the PPI Products, including the Plaintiff were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

ANSWER: Takeda denies the allegations of paragraph 352.

353. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: Takeda denies the allegations of paragraph 353.

354. As a direct and proximate result of the foregoing, Plaintiff are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§

2307.72(B).

ANSWER: Takeda denies the allegations of paragraph 354.

355. Further, as a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries; and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 355.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

357. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 357.

358. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious

kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 358.

359. Defendants expressly warranted that their PPI Products were safe and effective to use.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 359.

360. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 360.

361. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

ANSWER: Takeda denies the allegations of paragraph 361.

362. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

ANSWER: Takeda denies the allegations of paragraph 362.

363. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

ANSWER: Takeda denies the allegations of paragraph 363.

364. Defendants breached their express warranty in one or more of the following ways:
- a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
 - b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
 - c. Defendants failed to adequately test their PPI Products; and,
 - d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

ANSWER: Takeda denies the allegations of paragraph 364, including all subparts.

365. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

ANSWER: Takeda denies the allegations of paragraph 365.

366. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 366.

367. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 367.

368. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

ANSWER: Takeda denies the allegations of paragraph 368.

369. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to

Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 369.

370. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

ANSWER: Takeda denies the allegations of paragraph 370.

371. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

ANSWER: Takeda denies the allegations of paragraph 371.

372. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

ANSWER: Takeda denies the allegations of paragraph 372.

373. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

ANSWER: Takeda denies the allegations of paragraph 373.

374. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 374.

375. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made

conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 375.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

377. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 377.

378. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

ANSWER: Takeda denies the allegations of paragraph 378.

379. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

ANSWER: Takeda denies the allegations of paragraph 379.

380. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 380.

381. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

ANSWER: Takeda denies the allegations of paragraph 381.

382. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

ANSWER: Takeda denies the allegations of paragraph 382.

383. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Takeda denies the allegations of paragraph 383.

384. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Takeda denies the allegations of paragraph 384.

385. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

ANSWER: Takeda denies the allegations of paragraph 385.

386. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a

dangerous risk when used as intended to cause serious kidney injuries.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 386.

387. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

ANSWER: Takeda denies the allegations of paragraph 387.

388. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 388.

389. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 389.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT X
NEGLIGENT MISREPRESENTATION

390. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

391. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 391.

392. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, it admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 392.

393. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and her healthcare providers, as to the health risks and consequences of the use of their PPI Products.

ANSWER: Takeda admits that, pursuant to FDA approval, TPA and TPUSA have been involved in the marketing and sale of the Takeda Products in the United States. Takeda denies the remaining allegations of paragraph 393.

394. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-

inflammatory drug-induced gastropathy.

ANSWER: Takeda denies the allegations of paragraph 394.

395. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demands for, as well as the ultimate prescription, purchase and use of their PPI Products.

ANSWER: Takeda admits that, pursuant to approval by the FDA, TPA and TPUSA have marketed the Takeda Products in the United States, including through direct-to-consumer advertisements. Takeda denies the remaining allegations of paragraph 395.

396. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 396.

397. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

ANSWER: Takeda denies the allegations of paragraph 397.

398. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of PPI Products, and therefore denies them. Takeda denies the remaining allegations of paragraph 398.

399. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 399.

400. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 400.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XI **FRAUD AND FRAUDULENT MISREPRESENTATION**

401. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

402. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

ANSWER: Takeda admits that the Takeda Products are safe and effective when

prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 402.

403. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

ANSWER: Takeda admits that, pursuant to approval by the FDA, it has marketed the Takeda Products in the United States. Takeda further admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 403.

404. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

ANSWER: Takeda denies the allegations of paragraph 404.

405. These representations made by Defendants were false and misleading.

ANSWER: Takeda denies the allegations of paragraph 405.

406. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

ANSWER: Takeda denies the allegations of paragraph 406.

407. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 407.

408. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of Takeda Products

and therefore denies them. Takeda denies the remaining allegations of paragraph 408.

409. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of Takeda Products and therefore denies them. Takeda denies the remaining allegations of paragraph 409.

410. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

ANSWER: Takeda denies the allegations of paragraph 410.

411. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: Takeda denies the allegations of paragraph 411.

412. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further the remaining allegations of paragraph 412.

413. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 413.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but

denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered “wherefore” paragraph.

COUNT XII
GROSS NEGLIGENCE

414. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

415. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants’ conduct:

- a. when viewed objectively from Defendants’ standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

ANSWER: Takeda denies the allegations of paragraph 415, including all subparts.

416. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

ANSWER: Takeda admits that Plaintiff seeks damages and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of paragraph 416.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys’ fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered “wherefore” paragraph.

COUNT XIII
FRAUDULENT CONCEALMENT

417. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

418. Prior to Plaintiff’s use of Defendants’ PPI Products and, during the period in which Plaintiff actually used Defendants’ PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff’s use of Takeda Products and therefore denies them. Takeda denies the remaining allegations of paragraph 418.

419. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants’ PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

ANSWER: Takeda denies that the Takeda Products cause kidney injuries, and further denies the remaining allegations of paragraph 419.

420. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

ANSWER: Takeda denies the allegations of paragraph 420.

421. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Takeda Products and therefore denies them. Takeda denies the remaining allegations of paragraph 421.

422. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

ANSWER: Takeda denies the allegations of paragraph 422.

423. Plaintiff and/or her healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

ANSWER: Takeda denies the allegations of paragraph 423.

424. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: Takeda denies the allegations of paragraph 424.

425. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 425.

426. Defendants also had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute

legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 426.

427. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

ANSWER: Takeda states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda admits that it complied with its duty under the law at all times. Takeda denies the remaining allegations of paragraph 427.

428. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

ANSWER: Takeda denies the allegations of paragraph 428.

429. Plaintiff's healthcare providers were not provided the necessary information by The Defendants to provide an adequate warning to the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 429.

430. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 430.

431. The PPI Products were improperly marketed to the Plaintiff and/or her healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

ANSWER: Takeda denies the allegations of paragraph 431.

432. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

ANSWER: Takeda denies the allegations of paragraph 432.

433. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and the Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

ANSWER: Takeda denies the allegations of paragraph 433.

434. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Takeda denies the remaining allegations of paragraph 434.

435. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Takeda denies the remaining allegations of paragraph 435.

436. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

ANSWER: Takeda denies the allegations of paragraph 436.

437. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

ANSWER: Takeda denies the allegations of paragraph 437.

438. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 438.

439. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

ANSWER: Takeda admits that the Takeda Products are safe and effective when prescribed and used in accordance with their FDA-approved labeling. Takeda denies the remaining allegations of paragraph 439.

440. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

ANSWER: Takeda denies the allegations of paragraph 440.

441. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further the remaining allegations of paragraph 441.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies

the remaining allegations of this unnumbered “wherefore” paragraph.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: Takeda incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

443. Plaintiff used Defendants’ PPI Products and suffered ascertainable losses as a result of Defendants’ actions in violation of the consumer protection laws.

ANSWER: Takeda lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff’s use of PPI Products and therefore denies them. Takeda denies the remaining allegations of paragraph 443.

444. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, Ohio Rev. Code Ann. §§ 1345.01.

ANSWER: Takeda states that the allegations of paragraph 444 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Takeda, Takeda denies them, including all subparts.

445. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Takeda denies that the Takeda Products cause kidney or other injuries, and further denies the remaining allegations of paragraph 445.

446. Defendants’ conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff’s healthcare providers. Defendants made

conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Takeda denies the allegations of paragraph 446.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of this unnumbered "wherefore" paragraph.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

ANSWER: Takeda admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Takeda further denies the remaining allegations of Plaintiff's Prayer for Relief.

AFFIRMATIVE AND OTHER DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Takeda in this matter. Takeda therefore asserts said defenses in order to

preserve the right to assert them. Upon completion of discovery, and if facts warrant, Takeda may withdraw any of these defenses as may be appropriate. Further, Takeda reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Takeda states as follows:

1. Plaintiff's Complaint against Takeda fails to state a claim upon which relief may be granted.
2. This Court lacks personal jurisdiction over Takeda with respect to Plaintiff's claims, and thus the Complaint should be dismissed for lack of jurisdiction.
3. Each and every claim alleged or raised in the Complaint is barred by the applicable statute of limitations, the applicable statute of repose, the doctrine of prescription, and/or is otherwise untimely.
4. Each and every claim alleged or raised in the Complaint is barred by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and Takeda's only obligation is to warn the prescribing health care provider, which obligation was fulfilled.
5. Takeda gives notice that, to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Takeda intends to rely upon same in defense of this action.
6. Each and every claim alleged or raised in the Complaint is barred by the doctrines of laches, estoppel, waiver, and/or statutory and regulatory compliance.
7. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature

or other intervening and/or supervening cause or causes, and any act or omission on the part of Takeda was not the proximate and/or competent producing cause of such alleged injuries and damages.

8. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses may have been caused, may have been solely caused, may be barred, and/or may be limited in whole or in part by the contributory negligence or comparative fault and/or comparative negligence of Plaintiff.

9. In the alternative, without waiving its denial of liability to Plaintiff, Takeda states that, assuming that 100% represents the total combined fault of the parties to this action, the fault on the part of Plaintiff was more than 50% of the total proximate cause of the alleged injuries and, therefore, there is no liability on the part of Takeda. In the alternative, in the event that it is found that fault on the part of Plaintiff is less than 50% of the proximate cause of the alleged injury, then the amount of the verdict awarded to Plaintiff must be reduced in accordance with the percentage of that fault.

10. If Plaintiff has sustained injuries or losses, as alleged in the Complaint, Plaintiff's claims regarding such injuries or losses may be barred or reduced by Plaintiff's knowingly, voluntarily, and/or willfully assuming the risk of any injury as the result of the consumption of, administration of, or exposure to the products at issue or any medicine or pharmaceutical preparation manufactured or distributed by another manufacturer.

11. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Takeda and over whom Takeda had no control and for whom Takeda may not be held accountable.

12. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by circumstances, events, or persons over whom Takeda had no authority or control and for which Takeda is not answerable in damages to Plaintiff.

13. To the extent Plaintiff's claims were caused by the actions, omissions, or products of persons or entities over whom Takeda has no dominion, authority, or control, Takeda is entitled to have its liability to the Plaintiff, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

14. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse or abuse of the products at issue after they left the control of Takeda.

15. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were the result of unavoidable circumstances that could not have been prevented by any person, including Takeda.

16. Takeda denies any liability, but if Takeda is ultimately found liable to Plaintiff, then Takeda shall only be liable for its equitable share of Plaintiff's recovery since any such liability would be insufficient to impose joint liability.

17. If Plaintiff recovers from Takeda, Takeda is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence of fault proximately caused or contributed to cause Plaintiff's alleged damages.

18. Any verdict of judgment rendered against Takeda must be reduced by the comparative fault of other persons or entities.

19. Any verdict of judgment rendered against Takeda must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part for any past or future loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

20. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by the off-label use of the products at issue that Takeda did not proscribe and for which Takeda is not legally responsible.

21. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated physical, physiological, medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions, or natural courses of conditions for which Takeda is not legally responsible

22. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

23. Plaintiff did not detrimentally rely on any labeling, warnings, or information concerning the Takeda Products.

24. Any warranties made by Takeda to Plaintiff were disclaimed.

25. To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are barred for lack of timely notice of any breach or alleged failure.

26. Takeda did not sell or distribute the Takeda Products directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims are therefore barred by lack of privity.

27. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

28. Any claim for breach of express warranty must fail because Plaintiff failed to allege any representations about the products at issue giving rise to an express warranty.

29. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Takeda in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of the Takeda Products, including adequate warnings and instructions with respect to the products' use included in the products' package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

30. Plaintiff cannot establish that any reasonable alternative design would have rendered the products at issue safer overall, and that the failure to adopt a reasonable alternative design rendered the products at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Product Liability.

31. Plaintiff cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risks of harm posed by the products at issue would have rendered the products safer overall, and that the failure to provide such alternative instructions or warnings rendered the products at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

32. Each and every claim alleged or raised in the Complaint is barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

33. Each and every claim alleged or raised in the Complaint is barred in whole or in part because legally adequate “directions or warnings” were provided as to the use of the products at issue and any other medicine or pharmaceutical preparation to which Plaintiff attribute Plaintiff’s alleged damages within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

34. Each and every claim alleged or raised in the Complaint is barred by Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

35. Each and every claim alleged or raised in the Complaint is barred by comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

36. Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of the products at issue.

37. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government, and/or the *Noerr-Pennington* doctrine.

38. Each and every claim alleged or raised in the Complaint is barred in whole or in part by Plaintiff’s failure to mitigate alleged damages.

39. Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate their claims to negligence.

40. All activities of Takeda as alleged in the Complaint were expressly authorized and/or regulated by a governmental agency. Therefore, Plaintiff's claims pertaining to any alleged misrepresentations or omissions are barred.

41. Each and every claim alleged or raised in the Complaint is barred because, if the products at issue were unsafe, which Takeda denies, then they were unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the products exceeded any apparent risk, given the scientific knowledge available when the products were marketed.

42. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical products at issue provide net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

43. Plaintiff, or Plaintiff's physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of the Takeda Products and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings provided by Takeda and others generally available in the medical and scientific literature. Therefore, Takeda had no duty to warn of any alleged danger or defect.

44. Plaintiff's claims are barred because the Takeda Products were consistent with and exceeded consumer expectations.

45. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

46. Takeda had a good faith belief in the lawfulness of its actions.

47. Takeda's advertisements and labeling with respect to the products at issue were not false or misleading and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution and Constitution of the State of Ohio.

48. The public interest in the benefit and availability of the products at issue precludes liability for risks, if any, resulting from any activities undertaken by Takeda, that were unavoidable, given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the products at issue, then such risk, if any, is outweighed by the benefit of the products.

49. Plaintiff's failure to warn claim is barred given that Takeda had no duty to warn of risks of which Takeda neither knew nor should have known at the time its products were designed, distributed, and manufactured.

50. At all relevant times, the products at issue were manufactured and distributed in a reasonable and prudent manner, based upon available medical and scientific knowledge, and further were processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

51. To the extent there were any risks associated with the use of the products at issue that Takeda knew or should have known and that gave rise to a duty to warn, Takeda at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

52. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

53. Each and every claim alleged or raised in the Complaint may be barred because Plaintiff failed to comply with the conditions precedent or subsequent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

54. Each and every claim alleged or raised in the Complaint may be barred in whole or in part by the doctrine of informed consent.

55. Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources.

56. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

57. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Takeda, if any, should be reduced accordingly.

58. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or release of claims.

59. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

60. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, or suppression

61. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Takeda and all of its activities with respect to the products at issue have been and are conducted under the supervision of the FDA.

62. Each and every claim alleged or raised in the Complaint and based on allegedly inadequate warnings is barred even if Takeda failed to provide adequate warnings with respect to known or potential dangers or risks associated with the use of the products, because physicians prescribing the products at issue either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or that should be known to members of the profession.

63. Any injuries or damages Plaintiff may have sustained may have been caused by a substantial change in the products at issue after leaving the possession, custody, and control of Takeda.

64. The common law claims and theories of liability set forth in the Complaint are barred by the doctrine of federal preemption. Takeda's conduct conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, each and every claim alleged or raised in the Complaint is barred in whole or in part under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

65. The New Drug Applications for the Takeda Products were approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such statutes and regulations by Takeda demonstrates that the Takeda Products were safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiff's claims against Takeda. Compliance with such statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of the Takeda Products, and that they were neither defective nor unreasonably dangerous.

66. Plaintiff's claims are barred because the Takeda Products were neither defective nor unreasonably dangerous in their design, manufacture or marketing and were reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiff's recovery.

67. The warnings and instructions accompanying the Takeda Products at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

68. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding the Takeda Products and other drugs in their class.

69. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

70. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

71. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

72. All labeling for the Takeda Products has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Plaintiff's claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent Plaintiff asserts that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ____ (2019). Plaintiff's claims also are preempted by federal law pursuant to the Supremacy Clause of

the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives. Additionally, Plaintiff's design defect claims are barred by the doctrine of federal preemption under *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

73. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

74. Plaintiff's attempt to collect damages from Takeda based on Plaintiff's alleged injuries caused by a product that Takeda may not have manufactured or sold violates Takeda's rights under the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the Ohio Constitution.

75. Plaintiff did not suffer any actual injury, loss, or damages because of Plaintiff's alleged use of the Takeda Products.

76. Plaintiff's claims may be barred, in whole or in part, because Takeda did not design, promote, or sell the products which form the basis of Plaintiff's claims.

77. All or part of the injuries, damages, and/or losses, if any, sustained by Plaintiff, if proven, were caused in whole or in part by the acts or omissions of others for whose conduct Takeda is not responsible and/or resulted from conditions or events unrelated to any conduct by Takeda.

78. Some or all of Plaintiff's claims and/or damages, if any, may be barred, limited, or offset by the law of other states that may govern under this jurisdiction's choice of law provisions and resulting application of law from other jurisdictions. These may include, without limitation,

another state's product liability statute, its applicable statute of limitations, its modified comparative fault doctrine, and limitations on the award of non-economic and punitive damages.

79. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

80. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages ("punitive damages") for the conduct that allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Takeda's rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and the applicable provisions of the Ohio Constitution.

81. Any claim by Plaintiff for punitive damages is in contravention of Takeda's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; similar provisions in the Ohio Constitution.

82. To the extent that Plaintiff seeks punitive damages, said claim is unconstitutionally vague and/or overly broad because of the lack of clear standards. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, and applicable provisions of the Ohio Constitution and Ohio state common law and public policies.

83. Plaintiff's claim for punitive damages against Takeda cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Takeda; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards. Any such verdict would violate Takeda's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable provisions of the Ohio Constitution, and also would be improper under Ohio common law and public policies.

84. Unless Takeda's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate Takeda's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable provisions of the Ohio Constitution, and also would be improper under the applicable state common law and public policies

85. To the extent that Plaintiff seeks punitive damages, Takeda specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*,

517 U.S. 559, 116 S. Ct. 1589 (1996) and subsequent cases, including *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

86. To the extent that Plaintiff seeks punitive damages, any award against Takeda on any grounds other than its conduct with regard to the product Plaintiff used would be improper under applicable constitutional principles.

87. No act or omission of Takeda was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiff or with conscious disregard and indifference to the rights, safety and welfare of Plaintiff, and, therefore, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

88. To the extent that Plaintiff seeks punitive damages, such claim is barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

89. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Takeda and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the Ohio Constitution.

90. With respect to Plaintiff's demand for punitive or exemplary damages, Takeda specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and Ohio state law.

91. Plaintiff's Complaint seeks damages in excess of those permitted by law. Takeda asserts any statutory or judicial protection from punitive or exemplary damages which is available under the applicable law, including applicable statutory or other caps or limitations on the recovery or punitive or exemplary damages, and any award of punitive or exemplary damages is barred.

92. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, because Plaintiff may lack capacity or standing to bring the claims alleged.

93. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Takeda to determine all of its legal, contractual, and equitable rights, Takeda reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent defenses ascertained through further investigation and discovery.

94. Takeda is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

95. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and Takeda hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

96. Takeda hereby pleads all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22-2307.29.

97. Plaintiff's claims are barred because the Takeda Products are "ethical drugs" as defined by Ohio Rev. Code Ann. § 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.

98. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in O.R.C. §§ 2315.22, et seq. and 2315.32-2315.36.

99. Plaintiff's recovery as against Takeda should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.

100. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.

101. Plaintiff's claims for punitive or exemplary damages as set forth in the complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).

102. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

103. Ohio's Consumer Sales Practices Act, Ohio Rev. C. §1345.12(C), specifically precludes claims for personal injury or death.

104. Plaintiff fails to state a claim for relief under Ohio Rev. Code Ann. §§ 1345.01, et seq.

105. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, et seq. is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

106. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, et seq. unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

107. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code § 2307.711.

108. All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct Takeda had no reason to anticipate and for whose conduct Takeda is not and were not responsible. Ohio Revised Code § 2307.22, et seq.

109. The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code § 2307.23.

110. One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Revised Code §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, et al.

111. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(D) because adequate warning and instruction were provided under Ohio Revised Code § 2307.76 concerning any unavoidably unsafe aspects of the product.

112. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

113. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Revised Code § 2307.75(F).

114. Plaintiff's inadequate warning claims are barred under Ohio Revised Code § 2307.76(B) because the alleged risk of which they claim is open, obvious, and/or a matter of common knowledge.

115. Takeda adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

116. Takeda is entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of applicable state and federal law.

JURY DEMAND

Takeda hereby demands a trial by jury by the maximum number of jurors permitted by law on all issues so triable.

PRAYER

WHEREFORE, having answered, Takeda requests that this Court enter judgment in its favor and against Plaintiff on all counts and allegations of the Complaint and that the Court award Takeda its costs and such other relief as it deems just and proper.

Dated:

Respectfully submitted,

By: /s/ Gregory D. Brunton

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America, Inc., Takeda Development Center
Americas, Inc., and Takeda
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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served on July 2, 2019 via electronic mail on the following:

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/s/ Gregory D. Brunton

Gregory Brunton (0061722)

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA BEHYMER,

Plaintiff,

ABBOTT LABORATORIES, *et al.*,

Defendants.

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Civil Action No. A1902638

**PLAINTIFF’S MEMORANDUM IN OPPOSITION TO DEFENDANTS’ MOTION
FOR AN EXTENSION OF TIME TO ANSWER OR OTHERWISE RESPOND TO
PLAINTIFF’S COMPLAINT**

Plaintiffs memorandum in opposition to Defendants’ Motion for an Extension of Time to Answer or Otherwise Respond to Plaintiff’s Complaint.

First, Defendants have had ample time to file such a motion and the last-minute filing hinders Plaintiff’s ability to reply. Defendants were served with Plaintiff’s Complaint on June 7th and 10th, 2019 respectively. Defendants requested a 60-day extension of time to Answer or otherwise Respond on June 21, 2019, and Plaintiffs denied this request the same day.

Defendants waited 25 days before raising this issue with the Court, knowing full well that Plaintiffs were entitled to a 14 day opposition period, the Holiday week and their time to Answer each occurring in the coming days.¹ When a party, such as Defendants, “believes that it may

¹ Another example of Defendants’ carelessness is their filing of dozens of inaccurate Notices of Removal, each consisting of over 100 pages over the past 24 hours. Defendants could have allocated these resources of their hundreds of lawyers on staff to assist with the Answers rather than rely on a last minute extension request being granted by this Court.



need extra time, it should immediately request an extension from the court.” Extending Time in State Court Litigation (OH), Practical Law Practice Note w-000-3353.

Defendants’ last minute filing hinders the Plaintiff’s right to file an opposition 14 days later pursuant to Rule 6(C) of the Ohio Rules of Civil Procedure and the Court’s ability to review dozens of Motions on the eve of July 4th. Ohio Civ.R. 6(C)(1). Short notices such as this “risks having the deadline lapse before the court has a chance to rule on the request and notify the requesting party whether it has received the extension.” Extending Time in State Court Litigation (OH), Practical Law Practice Note w-000-3353.

Secondly, there is a history of denying these requests in this litigation. On its face, it may seem that Plaintiff’s counsel’s opposition and denial of Defendants’ request for an extension of time to Answer or Respond is unwarranted given the common courtesy that is usually afforded for such a request. However, the Parties in this matter have a three year history in the PPI litigation and, over the past three months, Plaintiffs in the Multi District Litigation have continuously requested short extensions from the Defendants regarding pleadings and discovery responses to no avail. Defendants denied such requests time and time again. Defendants’ reasoning was that Plaintiffs have long known of these deadlines and should have planned accordingly. Defendants’ cavalier attitude to treat their adversary, and the Court given the timing of these filings, should not be ignored.

Thirdly, there is a procedural deficiency. Defendants did not adhere to the local rules for the Court of Common Pleas in filing their Motion for Extension of Time. Rule 12 requires that the party moving to obtain an extension of time affirmatively state that “no prior extension has been granted.” Loc.R. 12 of the Court of Common Pleas of Hamilton County. Defendants have failed to meet this requirement, and, therefore, the Defendants’ Motion should be denied based

on the trial court's discretion over the matter. *See Weller v. Weller*, 115 Ohio App.3d 173, 684 N.E.2d 1284 (6th Dist.1996) ("Whether to grant or deny a motion to extend a court-ordered deadline or a motion to strike an untimely filed motion is a decision committed to the trial court's sound discretion.")

Lastly, Defendants' Motion alludes to the fact that these filings were voluminous and that they were unfamiliar within this litigation. This is far from the truth. Plaintiff's Complaint is substantially similar, if not nearly identical, to Complaints filed over the past three years of litigation for this matter. By way of background, on August 2, 2017, the Judicial Panel on Multidistrict Litigation ordered that PPI-related cases be coordinated in an MDL for pre-trial proceedings in the District of New Jersey. The Defendants have familiarized themselves with PPI complaints through MDL pleadings since this time, if not earlier as the first PPI cases were filed in May 2016. The factual allegations in the Plaintiff's Complaint and the Plaintiff's Master Long Form Complaint in the MDL mirror one another, and the majority of the causes of action are also identical. In Plaintiff's Complaint totaling approximately 70 pages, 17 pages of those factual allegations match 16 pages of factual allegations in the Master Long Form Complaint. Additionally, there are 12 matching causes of action between the Complaints out of 15 causes of action total in the Plaintiff's Complaint. The three counts that do not match are collectively three pages long. There are currently over 10,000 cases pending in the MDL and other State Court venues across the Country. Defendants have familiarized themselves with the arguments brought in this litigation. Unlike Ohio cases where the defendants were granted additional time to reply to new and numerous allegations in a complaint. *See Serra v. Guitar Ctr., Inc.*, 9th Distr. Lorain No. 16CA010949, 2017 Ohio 7789, ¶ 10-12 (where the court held that the trial court did not show abuse of discretion in granting a motion for an extension of time to reply to a

complaint which included 23 counts). It is unclear why Defendants require additional time to reply to familiar allegations that are not novel to this Plaintiff.

WHEREFORE, for the reasons stated herein, Plaintiff respectfully requests this Court deny Defendants' Motion in full.

Dated: July 3, 2019

/s/ John D. Holschuh, Jr.

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CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail Notice List.

/s/ John D. Holschuh
John D. Holschuh (0095377)

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

This Document Relates To:

TERESA A. BEHYMER

29 Richmond Drive
Westchester, OH 45069

Plaintiff,

vs.

ABBOTT LABORATORIES, ET AL.,

Defendants.

CASE NO: A 1902638

Judge

**ANSWER AND AFFIRMATIVE
DEFENSES OF ABBOTT
LABORATORIES**

JURY DEMAND ENDORSED HEREON

Defendant Abbott Laboratories (“Abbott”), by and through its attorneys, answers Plaintiff’s Complaint as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants’ defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys’ investigative efforts to date, regarding Defendants’ prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, “the PPI Products” or “PPIs”).

Abbott admits that Plaintiff seeks damages and other relief against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPIs.” Abbott denies that Plaintiff is entitled to judgment, damages, or relief of any kind and further denies the remaining allegations of paragraph 1.

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.



VERIFY RECORD

Abbott states that the allegations of paragraph 2 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

Abbott denies the allegations of paragraph 3.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. To the extent a response is required, Abbott admits that Plaintiff has brought a personal injury action against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPI’s.” Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott denies that it is liable to Plaintiff for any claims in any personal injury action and further denies any remaining allegations of paragraph 4 that are directed to it.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott

admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Because the remaining allegations of paragraph 5 are vague and ambiguous as applied to Abbott, they are denied.

PARTIES, JURISDICTION & VENUE

6. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court. The amount in controversy exceeds TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), exclusive of interest and costs, the jurisdictional minimum of this Court.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, it admits that Plaintiff purports to seek an amount in controversy that exceeds \$25,000, exclusive of interest and costs. Abbott denies the remaining allegations of paragraph 6.

I. PLAINTIFF

7. Plaintiff, Teresa A. Behymer, resides in Westchester, Ohio and resided in Westchester, Ohio at all times relevant.

a. Plaintiff, Teresa A. Behymer ingested the following PPI products sold by the Defendants from at least approximately January 2014 to December 2018: Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

b. As a direct and proximate result of Plaintiff's use of the PPI(s), Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix, Plaintiff has suffered and was treated for, Chronic Kidney Disease ("CKD") in approximately August 2016 with related sequelae.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff, and therefore denies them. Abbott denies the remaining allegations of paragraph 7, including all subparts.

II. DEFENDANTS

8. Defendant Abbott Laboratories (“Defendant Abbott”) is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

Abbott admits the allegations of paragraph 8.

9. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

Abbott admits that, at various times in the past, Abbott researched, tested, packaged, marketed and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott specifically denies that it manufactured Prevacid® and further denies the remaining allegations of paragraph 9.

10. Defendant Abbott manufactures and markets Prevacid in the United States.

Abbott admits that, at various times in the past, Abbott marketed and/or promoted Prevacid® in the United States but specifically denies that it manufactured Prevacid®, and denies any remaining allegations of paragraph 10.

11. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in each of the States and the District of Columbia.

Abbott denies the remaining allegations of paragraph 11.

12. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

Abbott admits that it has received revenue from the sale of Prevacid® in the United States. Abbott states that the phrase “substantial revenue” is vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Abbott

denies any remaining or inconsistent allegations of paragraph 12.

13. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

Abbott states that the phrases “its acts,” “consequence,” and “substantial revenue” are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Abbott denies the remaining allegations of paragraph 13.

14. Defendant AstraZeneca Pharmaceuticals LP (“AZ Pharm”) is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore denies them.

15. Defendant AstraZeneca LP (“AZ LP”) is, and at all times relevant to this action, has been a limited partnership organized under the laws of Delaware having a principal place of business in Delaware, whose ultimate parent company is AstraZeneca PLC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore denies them.

16. Defendants AZ Pharm and AZ LP are referred to collectively herein as “AZ Defendants.”

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott admits that Plaintiff purports to refer to “AZ Pharm” and “AZ LP” collectively as the “AZ

Defendants” in this Complaint. Abbott denies any remaining allegations in paragraph 16.

17. Each of the AZ Defendants was the agent and employee of the other AZ Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other AZ Defendants’ actual and implied permission, consent, authorization and approval.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore denies them.

18. The AZ Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18, and therefore denies them.

19. As a part of their business and at all relevant times, the AZ Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19, and therefore denies them.

20. In 1982, the AZ Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 20, and therefore denies them.

21. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21, and therefore denies them.

22. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec which, by the year 2000, was the most widely prescribed drug in the world.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23, and therefore denies them.

24. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25, and therefore denies them.

26. In an agreement reached in December 1997, the AstraZeneca Defendants entered into a co-promotion agreement with the Procter & Gamble Defendants granting the Procter & Gamble Defendants the right to market Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec and the Procter & Gamble Defendants market and sell Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27, and therefore denies them.

28. Pursuant to the terms of the co-promotion agreement, the Procter & Gamble Defendants marketed and sold Prilosec from at least December 8, 1997 through January 12, 2001.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. In 2006, the FDA approved New Drug Application (“NDA”) 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29, and therefore denies them.

30. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30, and therefore denies them.

31. Defendant AZ LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31, and therefore denies them.

32. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 32, and therefore denies them.

33. In anticipation of the expiration of the patent for prescription Prilosec, the AZ

Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 33, and therefore denies them.

34. In December 1999, Defendant AZ Pharm submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34, and therefore denies them.

35. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 35, and therefore denies them.

36. Defendant AZ Pharm is also the holder of approved NDAs 021957 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 36, and therefore denies them.

37. The AZ Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37, and therefore denies them.

38. In 2003, the AZ Defendants spent \$260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 38, and therefore denies them.

39. The AZ Defendants have transacted and conducted business related to PPI products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 39, and therefore denies them.

40. The AZ Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was \$2.7 billion and world-wide was \$3.9 billion.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 40, and therefore denies them.

41. The AZ Defendants have expected or should have expected their acts to have

consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPIs.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 41, and therefore denies them.

42. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 42, and therefore denies them.

43. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, pursuant to an agreement with the Novartis Defendants, obtained the rights to market and sell the over-the-counter medication Prevacid 24Hr.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 43, and therefore denies them.

44. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, in collaboration and amongst themselves, designed and developed Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 44, and therefore denies them.

45. As a part of their business and at all relevant times, Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 45, and therefore denies them.

46. Defendant GSK Consumer Healthcare (US) IP LLC is the holder of approved NDA 022327 for Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46, and therefore denies them.

47. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC manufacture and market Prevacid 24HR in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 47, and therefore denies them.

48. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 48, and therefore denies them.

49. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 49, and therefore denies them.

50. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 50, and therefore denies them.

51. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter “Defendant Merck”) is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51, and therefore denies them.

52. In 1982, Defendant Merck entered into an agreement with the AZ Defendants, under the terms of which Defendant Merck developed and marketed the AZ Defendants’ products, including Nexium and Prilosec products, under a royalty-bearing license.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 52, and therefore denies them.

53. In 1993, Merck's total sales of the AstraZeneca Defendants' products reached a level that triggered the first step in the establishment of a joint venture business (the "Joint Venture") in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 53, and therefore denies them.

54. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 54, and therefore denies them.

55. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 55, and therefore denies them.

56. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 56, and therefore denies them.

57. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 57, and therefore denies them.

58. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 58, and therefore denies them.

59. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 59, and therefore denies them.

60. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 60, and therefore denies them.

61. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 61, and therefore denies them.

62. Defendant Merck manufactures and markets Nexium products in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 62, and therefore denies them.

63. Defendant Merck manufactures and markets Prilosec products in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 63, and therefore denies them.

64. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 64, and therefore denies them.

65. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 65, and therefore denies them.

66. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 66, and therefore denies them.

67. Defendant Novartis Corporation is and, at all times relevant to this action, has been a New York corporation having a principal place of business in East Hanover, NJ.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 67, and therefore denies them.

68. Defendant Novartis Pharmaceuticals Corporation is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, NJ 07936.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 68, and therefore denies them.

69. Defendant Novartis Institutes for Biomedical Research, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business at 250 Massachusetts Avenue, Cambridge, MA 02139.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69, and therefore denies them.

70. Defendant Novartis Vaccines and Diagnostics, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business in East Hanover, NJ.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70, and therefore denies them.

71. Defendant Novartis Corporation is the parent/holding company of Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 71, and therefore denies them.

72. At all relevant times, Defendant Novartis Corporation has exercised and exercises dominion and control over Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 72, and therefore denies them.

73. Defendants Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc. are herein referred to collectively as “Novartis Defendants.”

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 73, and therefore denies them.

74. Each of the Novartis Defendants was the agent and employee of the other Novartis Defendants, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Novartis Defendants’ actual and implied permission, consent, authorization and approval.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 74, and therefore denies them.

75. In 2005, the Novartis Defendants obtained the rights to market the over-the-counter version of Prevacid, Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 75, and therefore denies them.

76. As part of their business and at all relevant times, the Novartis Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 76, and therefore denies them.

77. The Novartis Defendants, in collaboration amongst themselves, designed and developed the Prevacid 24 HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 77, and therefore denies them.

78. Defendant Novartis Pharmaceuticals Corporation has been the holder of approved NDA 022327 for Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 78, and therefore denies them.

79. The Novartis Defendants manufacture and market Prevacid 24HR in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 79, and therefore denies them.

80. The Novartis Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 80, and therefore denies them.

81. The Novartis Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 81, and therefore denies them.

82. The Novartis Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 82, and therefore denies them.

83. Defendant Pfizer Inc. is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 235 East 42nd Street, New York, NY 10017.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 83, and therefore denies them.

84. As a part of their business and at all relevant times, Defendant Pfizer Inc. has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of the drugs Protonix (pantoprazole) and Nexium 24HR.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 84, and therefore denies them.

85. In or about 2012, Defendant Pfizer Inc. entered into a marketing agreement with the AstraZeneca Defendants whereby Defendant Pfizer Inc. acquired the rights to market Nexium 24HR products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 85, and therefore denies them.

86. On or about March 28, 2014, Defendant Pfizer Inc., in collaboration with and pursuant to its marketing agreement with the AstraZeneca Defendants, was granted FDA approval to market Nexium 24HR products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 86, and therefore denies them.

87. Defendant Pfizer Inc. makes Nexium 24HR available for purchase in the United States in and around 2014 and continues to manufacture and market Nexium 24HR in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 87, and therefore denies them.

88. Defendant Pfizer Inc. manufactures and markets Protonix in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 88, and therefore denies them.

89. Defendant Pfizer Inc. has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to

Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 89, and therefore denies them.

90. Defendant Pfizer Inc. has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 90, and therefore denies them.

91. Defendant Pfizer Inc. has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 91, and therefore denies them.

92. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 92, and therefore denies them.

93. Defendant The Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

Abbott states that the allegations of this paragraph do not state any allegations as to

Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 93, and therefore denies them.

94. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests of and Defendant The Procter & Gamble Manufacturing Company.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 94, and therefore denies them.

95. Defendant The Procter & Gamble Company and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott admits that Plaintiff purports to refer to The Procter & Gamble Company and Procter & Gamble Manufacturing Company collectively as the “Procter & Gamble Defendants” in this Complaint. Abbott denies any remaining allegations in paragraph 95.

96. Each of the Procter & Gamble Defendants was the agent and employee of the Other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant’s actual and implied permission, consent, authorization and approval.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96, and therefore denies them.

97. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 97, and therefore denies them.

98. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 98, and therefore denies them.

99. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 99, and therefore denies them.

100. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 100, and therefore denies them.

101. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 101, and therefore denies them.

102. The Procter & Gamble Defendants made Prilosec OTC available for purchase in the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 102, and therefore denies them.

103. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 103, and therefore denies them.

104. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 104, and therefore denies them.

105. The Procter & Gamble Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prilosec OTC.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 105, and therefore denies them.

106. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 106, and therefore denies them.

107. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 107, and therefore denies them.

108. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 108, and therefore denies them.

109. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 109, and therefore denies them.

110. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 110, and therefore denies them.

111. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 111, and therefore denies them.

112. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 112, and therefore denies them.

113. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals

America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

Abbott states that the allegations of this paragraph do not require a response. If a response is required, Abbott admits that Plaintiff purports to refer to Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., Takeda California, Inc., Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc., and Takeda Pharmaceutical Company collectively as “Takeda Defendants” in this Complaint. Abbott denies any remaining allegations in paragraph 113.

114. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 114, and therefore denies them.

115. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of, Prevacid, Prevacid 24HR and Protonix products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 115, and therefore denies them.

116. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid, Prevacid 24HR, and Protonix products.

Abbott states that the allegations of this paragraph do not state any allegations as to

Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 116, and therefore denies them.

117. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 117, and therefore denies them.

118. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 118, and therefore denies them.

119. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 119, and therefore denies them.

120. The Takeda Defendants manufacture and market each of these Protonix formulations in the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 120, and therefore denies them.

121. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 121, and therefore denies them.

122. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 122, and therefore denies them.

123. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them. Abbott denies any remaining allegations in paragraph 123.

124. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are

construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 124 at this time, and therefore denies them. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

125. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 125 at this time, because jurisdictional issues are dependent on the facts of each case. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

FACTUAL ALLEGATIONS

126. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 126 at this time, and therefore denies them.

127. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

Abbott admits that Prevacid® is FDA-approved and that the mechanism of action is outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 127 at this time, and therefore denies them.

128. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

Abbott states that the allegations of this paragraph are vague and ambiguous as written. As such, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 128, and therefore denies them.

129. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 129, and therefore denies them.

130. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 130, and therefore denies them.

131. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 131, and therefore denies them.

132. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

Abbott admits that Dr. Stephen Ruffenach and other researchers from the University

of Arizona Health Sciences Center published an article in the American Journal of Medicine in 1992 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 132.

133. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

Abbott states that the allegations of paragraph 133 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

134. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

Abbott states that the allegations of paragraph 134 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

135. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

Abbott admits that researchers from the Yale School of Medicine published an article in the International Society of Nephrology's Kidney International in 2006 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 135.

136. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

Abbott admits that Dr. F. Sierra and others published an article in the Journal of Alimentary Pharmacology and Therapeutics in 2007 and states that the article speaks for

itself. Abbott denies any remaining or inconsistent allegations of paragraph 136.

137. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, “where PPI-induced AIN is disproportionately present in the database.” Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

Abbott states that Dr. Harmark and others published an article in the British Journal of Clinical Pharmacology in 2007 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 137.

138. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen’s Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

Abbott admits, on information and belief, that on August 23, 2011, Public Citizen filed a petition with the FDA requesting that additional warnings be added to the labeling of PPI products. Abbott denies the validity of this citizen’s petition and further denies the remaining allegations of paragraph 138.

139. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

Abbott admits, on information and belief, that the Public Citizen petition filed with the FDA on August 23, 2011 stated, for example, that “[i]nformation regarding the potential for drug-induced acute interstitial nephritis, seen in at least 60 case reports, should be included in the appropriate section. There is currently no detailed risk information on any PPI for this adverse effect.” Abbott denies the validity of this citizen’s petition and further denies the remaining allegations of paragraph 139.

140. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

Abbott admits, on information and belief, that on October 31, 2014, the FDA

responded to Public Citizen’s petition by stating that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 140.

141. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen’s petition by stating that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 141.

142. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 142, and therefore denies them.

143. To this date, Defendants’ over-the-counter PPI Products do not include a warning or any risk information about AIN.

Abbott states that the allegations of paragraph 143 do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted any “over-the counter PPI Products” as alleged and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to the identification of the products at issue in this paragraph.

Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

144. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

Abbott denies the allegations of paragraph 144.

145. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

Abbott denies the allegations of paragraph 145.

146. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

Abbott denies that the mechanism by which drugs may cause AIN has been established. Abbott further denies any remaining or inconsistent allegations of paragraph 146.

147. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

Abbott admits that not every patient diagnosed with AIN presents with a fever.

Abbott denies any remaining or inconsistent allegations of paragraph 147.

148. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

Abbott admits that the publications referenced in this paragraph are in the published literature and state that these publications speak for themselves. Abbott denies that the

mechanism by which drugs may cause AIN has been established and further denies any remaining or inconsistent allegations of paragraph 148.

149. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 149, and therefore denies them.

150. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure. Abbott lacks knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 150, and therefore denies them.

151. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 151, and therefore denies them.

152. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

Abbott denies that Prevacid® causes acute kidney injury or renal failure. Abbott admits that Acute Kidney Injury is characterized by acute and sudden renal failure by which

the kidneys fail to filtrate properly. Abbott denies any remaining allegations of paragraph 152.

153. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and denies the allegations of paragraph 153.

154. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and denies them. Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies any remaining allegations of paragraph 154.

155. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

Abbott admits, on information and belief, that Prevacid®’s product labeling does not explicitly reference AKI as defined in the Plaintiff’s Complaint. Abbott further denies any remaining or inconsistent allegations of paragraph 155.

156. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

Abbott denies the allegations of paragraph 156.

157. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

Abbott admits that chronic kidney disease is the gradual loss of kidney function. Abbott denies that Prevacid® causes chronic kidney disease and further denies any

remaining or inconsistent allegations of paragraph 157.

158. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

Abbott admits that chronic kidney disease can, but does not always, lead to the development of end stage renal disease. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 158.

159. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

Abbott admits that a study was published in the Journal of the American Medical Association in January 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 159.

160. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

Abbott admits that a study was published in the Journal of the American Society of Nephrology in February 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease, progression of kidney disease, or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 160.

161. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

Abbott admits that a study was published in the Journal of Nephrology in April 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 161.

162. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

Abbott denies the allegations characterizing chronic kidney disease in paragraph 162 and further denies that Prevacid® causes chronic kidney disease or end stage renal failure.

163. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int’l 1482 (2017).

Abbott admits that a study was published in the Kidney International in 2017 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 163.

164. To date, the labeling for Defendants’ PPI Products lack adequate risk information about CKD.

Abbott denies the allegations of paragraph 164.

165. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

Abbott denies the allegations of paragraph 165.

166. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

Abbott denies the allegations of paragraph 166.

167. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted “omeprazole/Prilosec” and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to “phenomenon.” Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 167, and therefore denies them.

168. Because PPI Products work by preventing the acidification of the stomach’s contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies’ acid production increases beyond their pre-PPI treatment levels.

Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 168.

169. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

Abbott denies the allegations of paragraph 169.

170. After Plaintiff’s discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

Abbott denies the allegations of paragraph 170.

171. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth of the allegations of paragraph 171 and therefore denies them.

172. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

Abbott denies the allegations of paragraph 172.

173. To date, the labeling for the Defendants’ respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

Abbott denies the allegations of paragraph 173.

174. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as “H₂ Blockers”) that were developed in the late 1960s. H₂ Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H₂ Blockers include Zantac, Pepcid and Tagamet. H₂ Blockers are not associated with an increased risk of kidney injuries.

Abbott denies the allegations of paragraph 174.

175. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

Abbott admits that Dr. Marks published an article in The Pharmaceutical Journal in 2016 and states that the article speaks for itself. Abbott denies any remaining allegations of paragraph 175.

176. Consumers, including Plaintiff, who have used Defendants’ PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

Abbott denies the allegations of paragraph 176.

177. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

Abbott denies the allegations of paragraph 177.

178. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

Abbott denies the allegations of paragraph 178.

179. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 179.

180. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 180.

181. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

Abbott denies the allegations of paragraph 181.

182. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

Abbott denies the allegations of paragraph 182.

183. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

Abbott denies the allegations of paragraph 183.

184. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

Abbott denies the allegations of paragraph 184.

185. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

Abbott denies the allegations of paragraph 185.

186. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 186.

187. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants'

respective PPI Products, and Defendants could have altered the same without FDA approval.

Abbott states that the allegations of paragraph 187 constitute legal conclusions to which no response is required. To the extent that the allegations are construed as factual allegations directed to Abbott, they are denied.

188. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

To the extent that the allegations of paragraph 188 are directed to Abbott, they are denied.

189. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

To the extent that the allegations of paragraph 189 are directed to Abbott, they are denied.

190. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

To the extent that the allegations of paragraph 190 are directed to Abbott, they are denied.

191. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

Abbott denies the allegations of paragraph 191.

192. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

To the extent that the allegations of paragraph 192 are directed to Abbott, Abbott denies them.

193. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

To the extent that the allegations of paragraph 193 are directed to Abbott, Abbott denies them.

194. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

To the extent that the allegations of paragraph 194 are directed to Abbott, Abbott denies them.

195. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 195.

196. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

Abbott denies the allegations of paragraph 196.

197. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;
- d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
- e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or

incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

- f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;
- g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;
- h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;
- i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;
- j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR § 201.66 because they were and are not informative and accurate;
- k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR § 201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;
- l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;
- m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;
- n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;
- o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;
- p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;
- q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

- r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;
- s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;
- t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;
- u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;
- v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;
- w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;
- x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;
- y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and
- z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.
- aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

Abbott states that the allegations of paragraph 197 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied, including all subparts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

199. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert tolling of relevant statutes of limitations, but denies that Plaintiff is entitled to such tolling. Abbott denies any remaining allegations of paragraph 199.

200. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert application of the discovery rule, but denies that Plaintiff is entitled to such application. Abbott denies any remaining allegations of paragraph 200.

201. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable

statutory limitations period.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 201 are construed as factual allegations directed to Abbott, they are denied.

202. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 202 are construed as factual allegations directed to Abbott, they are denied.

203. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 203.

204. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

To the extent that the allegations of paragraph 204 are directed to Abbott, they are denied.

205. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

To the extent that the allegations of paragraph 205 are directed to Abbott, they are denied.

206. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

To the extent that the allegations of paragraph 206 are directed to Abbott, they are denied.

207. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products and regarding Plaintiff's medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 207.

208. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products and regarding Plaintiff's medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 208.

209. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 209.

210. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

To the extent the allegations of paragraph 210 are directed to Abbott, they are denied.

211. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI. Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products or medical conditions. Abbott denies any remaining allegations of paragraph 211.

CAUSES OF ACTION

COUNT I **STRICT PRODUCT LIABILITY**

212. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

213. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

Abbott denies the allegations of paragraph 213 and specifically denies that it manufactured Prevacid® and that Prevacid® was defective or unreasonably dangerous.

214. At the time of the Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable

users, including the Plaintiff.

Abbott denies the allegations of paragraph 214 and specifically denies that Prevacid® was defective or unreasonably dangerous.

215. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 215, and specifically denies that it manufactured Prevacid®.

216. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® "did reach" users without substantial change in the condition in which it was distributed, and therefore denies them. Abbott denies the remaining allegations of paragraph 216.

217. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including the Plaintiff.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 217, and specifically denies that it

manufactured Prevacid®.

218. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

Abbott denies the allegations of paragraph 218, and specifically denies that Prevacid® is or was defective.

219. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

Abbott denies the allegations of paragraph 219, and specifically denies that Prevacid® is or was defective or unsafe.

220. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

Abbott denies the allegations of paragraph 220, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

221. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

Abbott denies the allegations of paragraph 221, and specifically denies that Prevacid® is or was defective, inherently dangerous, or unsafe.

222. At the time, the Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 222, and therefore denies them.

223. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

Abbott denies the allegations of paragraph 223.

224. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining or inconsistent allegations of paragraph 224.

225. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

Abbott denies the allegations of paragraph 225.

226. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

Abbott denies the allegations of paragraph 226, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

227. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

Abbott denies the allegations of paragraph 227, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

228. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

Abbott denies the allegations of paragraph 228.

229. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI

Products' defects herein mentioned and perceived their danger.

Abbott denies the allegations of paragraph 229, and specifically denies that Prevacid® is or was defective or dangerous.

230. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

Abbott denies the allegations of paragraph 230.

231. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

Abbott denies the remaining allegations of paragraph 231, and specifically denies that Prevacid® is or was defective or dangerous.

232. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

Abbott denies the allegations of paragraph 232, and specifically denies that Prevacid® is or was defective or dangerous.

233. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

Abbott denies the allegations of paragraph 233, and specifically denies that Prevacid® is or was defective.

234. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have

known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

Abbott denies the allegations of paragraph 234, and specifically denies that Prevacid® is or was defective.

235. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 235, and therefore denies them.

236. Plaintiff did not misuse or materially alter the PPI Products.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 236, and therefore denies them.

237. Defendants are strictly liable for the Plaintiff's injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

Abbott denies the allegations of paragraph 237, including all subparts, and specifically denies that Prevacid® is or was defective or dangerous.

238. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

Abbott denies the allegations of paragraph 238.

239. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

Abbott denies the allegations of paragraph 239.

240. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

Abbott denies the allegations of paragraph 240.

241. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies the allegations of paragraph 241.

242. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, the Plaintiff, and/or the Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 242.

WHEREFORE, the Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

243. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. The Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully

set forth herein.

244. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

Abbott denies the allegations of paragraph 244, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

245. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

Abbott denies the allegations of paragraph 245.

246. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

Abbott denies the allegations of paragraph 246.

247. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 247, and therefore denies them.

248. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

Abbott denies the allegations of paragraph 248.

249. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® "did reach" intended consumers, including Plaintiff, without substantial change in the condition in which it was distributed, and therefore denies them. Abbott specifically

denies that it was a manufacturer of Prevacid®, and further denies any remaining allegations of paragraph 249.

250. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

Abbott denies the allegations of paragraph 250.

251. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

Abbott denies the allegations of paragraph 251, and specifically denies that Prevacid® is or was defective or dangerous.

252. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

Abbott denies the allegations of paragraph 252, and specifically denies that Prevacid® is or was defective or unsafe.

253. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

Abbott denies the allegations of paragraph 253.

254. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

Abbott denies the allegations of paragraph 254.

255. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiff specifically were not aware of these risks, nor would they expect such risks.

Abbott denies the allegations of paragraph 255.

256. The PPI Products manufactured and supplied by Defendants were defective in

design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with the design or formulation of the PPI Products, as defined by Ohio Rev. Code. §§ 2307.75(C), or they were more dangerous than an ordinary consumer would expect.

Abbott denies the allegations of paragraph 256.

257. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, as defined at Ohio Rev. Code. §§ 2307.75(B)(1)-(5), include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury, as defined at Ohio Rev. Code §§ 2307.75(B)(4), specifically, the risk of kidney injuries.
- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

Abbott denies the allegations of paragraph 257, including all subparts.

258. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

Abbott denies the allegations of paragraph 258.

259. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

Abbott denies the allegations of paragraph 259.

260. The intended or actual utility of PPI Products is not of such benefit to justify the

risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

Abbott denies the allegations of paragraph 260.

261. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

Abbott denies the allegations of paragraph 261.

262. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

Abbott denies the allegations of paragraph 262.

263. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 263.

264. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

Abbott denies the allegations of paragraph 264 and specifically denies that Prevacid®

is or was unreasonably dangerous.

265. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

Abbott denies the allegations of paragraph 265 and specifically denies that Prevacid®

is or was dangerous.

266. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

Abbott denies the allegations of paragraph 266 and specifically denies that Prevacid®

is or was dangerous.

267. The PPI Products' design is defective and unsafe, and Defendants knew or had

reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

Abbott denies the allegations of paragraph 267 and specifically denies that Prevacid® is or was defective or unsafe.

268. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 268.

269. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 269.

270. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 270.

271. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

Abbott denies the allegations of paragraph 271.

272. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 272.

273. The warnings and instructions for use accompanying the PPI Products were

negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

Abbott denies the allegations of paragraph 273.

274. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff's injuries and damages.

Abbott denies the allegations of paragraph 274.

275. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 275 and specifically denies that Prevacid® is defective in design or formulation, or unsafe.

276. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

Abbott denies the allegations of paragraph 276.

277. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

Abbott denies the allegations of paragraph 277.

278. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

Abbott denies the allegations of paragraph 278.

279. The defective nature of the PPI Products was a substantial factor in causing Plaintiff's injuries.

Abbott denies the allegations of paragraph 279 and specifically denies that Prevacid® is or was defective.

280. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies the allegations of paragraph 280.

281. Defendants' conduct, as described herein, was extreme and outrageous.

Abbott denies the allegations of paragraph 281.

282. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 282.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

284. Defendants manufactured, distributed and/or sold the PPI Products that were

dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

Abbott denies the allegations of paragraph 284, specifically denies that Prevacid® is or was dangerous or causes kidney or other personal injuries, and specifically denies that it manufactured Prevacid®.

285. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

Abbott denies the allegations of paragraph 285 and specifically denies that Prevacid® is or was defective.

286. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 286.

287. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 287.

288. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 288.

289. The risks of PPI Products were not open and obvious, as defined at Ohio Rev. Code Code §§ 2307.76(B).

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 289.

290. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

Abbott denies the allegations of paragraph 290.

291. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

Abbott denies the allegations of paragraph 291 and specifically denies that it is or was a manufacturer of Prevacid®.

292. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

Abbott denies that Prevacid® causes kidney injuries, denies that Prevacid® is or was defective or unreasonably dangerous, and further denies the remaining allegations of paragraph 292.

293. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

Abbott denies the allegations of paragraph 293, and specifically denies Prevacid® is or was defective or unreasonably dangerous.

294. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 294, and therefore denies them.

295. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

Abbott denies the allegations of paragraph 295, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

296. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 296, and specifically denies that it is or was a manufacturer of Prevacid®.

297. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

Abbott denies the allegations of paragraph 297.

298. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

Abbott denies the allegations of paragraph 298.

299. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its

duty under the law at all times. Abbott denies the remaining allegations of paragraph 299.

300. Had Plaintiff and/or her healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

Abbott denies the allegations of paragraph 300.

301. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

Abbott denies the allegations of paragraph 301.

302. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

Abbott denies the allegations of paragraph 302.

303. Plaintiff and her healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

Abbott denies the allegations of paragraph 303.

304. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

Abbott denies the allegations of paragraph 304.

305. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

Abbott denies the allegations of paragraph 305.

306. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

Abbott denies the allegations of paragraph 306.

307. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and

frequency of use.

Abbott denies the allegations of paragraph 307.

308. Defendants' conduct as described herein was a substantial factor in causing Plaintiff's injuries.

Abbott denies the allegations of paragraph 308.

309. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

Abbott denies the allegations of paragraph 309.

310. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 310.

311. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

Abbott denies the allegations of paragraph 311.

312. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 312.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered “wherefore” paragraph.

COUNT IV
NEGLIGENCE

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

314. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 314.

315. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff’s injuries and/or presented an unreasonably high risk of injury.

Abbott denies the allegations of paragraph 315.

316. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;

- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
- k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
- m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
- n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
- o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
- p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
- q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;

- r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
- s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
- t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
- v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
- w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
- x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
- y. Failing to use due care under the circumstances; and
- z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

Abbott denies that Prevacid® causes kidney or other injuries and further denies the remaining allegations of paragraph 316, including all subparts.

317. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 317.

318. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

Abbott denies the allegations of paragraph 318.

319. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

Abbott denies the allegations of paragraph 319.

320. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants

continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

Abbott denies the allegations of paragraph 320.

321. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

Abbott denies the allegations of paragraph 321.

322. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

Abbott denies the allegations of paragraph 322.

323. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

Abbott denies the allegations of paragraph 323.

324. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

Abbott denies the allegations of paragraph 324.

325. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies the allegations of paragraph 325.

326. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 326.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT V
NEGLIGENCE PER SE

327. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

328. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

Abbott states that the allegations of paragraph 328 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

329. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

Abbott states that the allegations of paragraph 329 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, they are denied.

330. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

Abbott denies the allegations of paragraph 330.

331. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

Abbott states that the allegations of paragraph 331 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, they are denied.

332. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

Abbott states that the allegations of paragraph 332 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, they are denied.

333. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 333.

334. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 334.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

336. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 336 and specifically denies that Prevacid® was unreasonably dangerous.

337. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

Abbott denies the allegations of paragraph 337.

338. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

Abbott denies the allegations of paragraph 338.

339. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

Abbott denies the allegations of paragraph 339.

340. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

Abbott denies the allegations of paragraph 340.

341. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

Abbott denies the allegations of paragraph 341.

342. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure caused by the use of the PPI Products.

Abbott denies the allegations of paragraph 342.

343. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

Abbott denies the allegations of paragraph 343.

344. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

Abbott denies the allegations of paragraph 344.

345. Defendants are strictly liable for the Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

Abbott denies the allegations of paragraph 345.

346. As a direct and proximate result of Defendants' wrongful actions and failure to test, the Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 346.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

347. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

348. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of PPI Products and made representations regarding the character or quality of PPI Products including but not limited to the fact that PPI Products were safe and effective in its ordinary use.

Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott denies the remaining allegations of paragraph 348, and specifically denies that it manufactured Prevacid®.

349. The PPI Products manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

Abbott denies the allegations of paragraph 349, and specifically denies that Prevacid® is or was defective.

350. These material misrepresentations made by the Defendants were false.

Abbott denies the allegations of paragraph 350.

351. Plaintiff justifiably relied upon Defendants' representations regarding PPI Products.

Abbott denies the allegations of paragraph 351.

352. Upon information and belief, the warnings provided to those who chose to use the PPI Products, including the Plaintiff were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

Abbott denies the allegations of paragraph 352.

353. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

Abbott denies the allegations of paragraph 353.

354. As a direct and proximate result of the foregoing, Plaintiff are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

Abbott denies the allegations of paragraph 354.

355. Further, as a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries; and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 355.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

357. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

Abbott denies the allegations of paragraph 357.

358. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 358.

359. Defendants expressly warranted that their PPI Products were safe and effective to use.

Abbott denies the allegations of paragraph 359.

360. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

Abbott denies the allegations of paragraph 360.

361. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

Abbott denies the allegations of paragraph 361.

362. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

Abbott denies the allegations of paragraph 362.

363. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

Abbott denies the allegations of paragraph 363.

364. Defendants breached their express warranty in one or more of the following ways:

- a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
- c. Defendants failed to adequately test their PPI Products; and,
- d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

Abbott denies the allegations of paragraph 364, including all subparts.

365. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

Abbott denies the allegations of paragraph 365.

366. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

Abbott denies the allegations of paragraph 366.

367. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 367.

368. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

Abbott denies the allegations of paragraph 368.

369. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

Abbott denies the allegations of paragraph 369.

370. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

Abbott denies the allegations of paragraph 370.

371. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

Abbott denies the allegations of paragraph 371.

372. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

Abbott denies the allegations of paragraph 372.

373. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

Abbott denies the allegations of paragraph 373.

374. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 374.

375. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 375.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies

that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered “wherefore” paragraph.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

377. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

Abbott denies the allegations of paragraph 377.

378. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

Abbott denies the allegations of paragraph 378.

379. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

Abbott denies the allegations of paragraph 379.

380. Plaintiff reasonably relied on Defendants’ representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

Abbott denies the allegations of paragraph 380.

381. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants’ promotional and advertising materials in their selection of the product for that particular use.

Abbott denies the allegations of paragraph 381.

382. Through aggressive healthcare provider promotion and patient advertising,

educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

Abbott denies the allegations of paragraph 382.

383. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

Abbott denies the allegations of paragraph 383.

384. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

Abbott denies the allegations of paragraph 384.

385. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

Abbott denies the allegations of paragraph 385.

386. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 386.

387. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

Abbott denies the allegations of paragraph 387.

388. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies the allegations of paragraph 388.

389. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with

knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 389.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT X
NEGLIGENT MISREPRESENTATION

390. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

391. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

Abbott denies the allegations of paragraph 391.

392. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

Abbott states that the allegations of this paragraph regarding duty constitute legal

conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 392.

393. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and her healthcare providers, as to the health risks and consequences of the use of their PPI Products.

Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 393.

394. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

Abbott denies the allegations of paragraph 394.

395. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demands for, as well as the ultimate prescription, purchase and use of their PPI Products.

Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 395.

396. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 396.

397. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

Abbott denies the allegations of paragraph 397.

398. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of PPI Products, and therefore denies them. Abbott denies the remaining allegations of paragraph 398.

399. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 399.

400. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 400.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XI
FRAUD AND FRAUDULENT MISREPRESENTATION

401. Plaintiff incorporates by reference each preceding and succeeding paragraph as

though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

402. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

Abbott denies the allegations of paragraph 402.

403. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 403.

404. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

Abbott denies the allegations of paragraph 404.

405. These representations made by Defendants were false and misleading.

Abbott denies the allegations of paragraph 405.

406. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

Abbott denies the allegations of paragraph 406.

407. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

Abbott denies the allegations of paragraph 407.

408. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably

believed them to be true.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 408.

409. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products, and therefore denies them. Abbott denies the remaining allegations of paragraph 409.

410. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

Abbott denies the allegations of paragraph 410.

411. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

Abbott denies the allegations of paragraph 411.

412. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 412.

413. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 413.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XII
GROSS NEGLIGENCE

414. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

415. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

Abbott denies the allegations of paragraph 415, including all subparts.

416. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

Abbott admits that Plaintiff seeks damages and other relief, but denies that Plaintiff

is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of paragraph 416.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XIII
FRAUDULENT CONCEALMENT

417. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

418. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 418.

419. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 419.

420. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

Abbott denies the allegations of paragraph 420.

421. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 421.

422. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

Abbott denies the allegations of paragraph 422.

423. Plaintiff and/or her healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

Abbott denies the allegations of paragraph 423.

424. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

Abbott denies the allegations of paragraph 424.

425. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are

construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 425.

426. Defendants also had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 426.

427. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 427.

428. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

Abbott denies the allegations of paragraph 428.

429. Plaintiff's healthcare providers were not provided the necessary information by The Defendants to provide an adequate warning to the Plaintiff.

Abbott denies the allegations of paragraph 429.

430. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

Abbott denies the allegations of paragraph 430.

431. The PPI Products were improperly marketed to the Plaintiff and/or her healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

Abbott denies the allegations of paragraph 431.

432. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

Abbott denies the allegations of paragraph 432.

433. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and the Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

Abbott denies the allegations of paragraph 433.

434. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 434.

435. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 435.

436. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

Abbott denies the allegations of paragraph 436.

437. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

Abbott denies the allegations of paragraph 437.

438. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

Abbott denies the allegations of paragraph 438.

439. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

Abbott denies the allegations of paragraph 439.

440. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

Abbott denies the allegations of paragraph 440.

441. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 441.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

443. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 443.

444. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, Ohio Rev. Code Ann. §§ 1345.01.

Abbott states that the allegations of paragraph 444 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies them.

445. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 445.

446. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Abbott denies the allegations of paragraph 446.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of Plaintiff's Prayer For Relief.

AFFIRMATIVE AND OTHER DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Abbott in this matter. Abbott therefore asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if facts warrant, Abbott

may withdraw any of these defenses as may be appropriate. Further, Abbott reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Abbott states as follows:

1. Plaintiff's Complaint against Abbott fails to state a claim upon which relief may be granted.
2. This Court lacks personal jurisdiction over Abbott with respect to Plaintiff's claims, and thus the Complaint should be dismissed.
3. Each and every claim alleged or raised in the Complaint is barred by the applicable statute of limitations, the applicable statute of repose, the doctrine of prescription, and/or is otherwise untimely.
4. Each and every claim alleged or raised in the Complaint is barred by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and Abbott's only obligation, if any, would be to warn the prescribing health care provider, which obligation was fulfilled.
5. Abbott gives notice that, to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Abbott intends to rely upon same in defense of this action.
6. Each and every claim alleged or raised in the Complaint is barred by the doctrines of laches, estoppel, waiver, and/or statutory and regulatory compliance.
7. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening and/or supervening cause or causes, and any act or omission on the part of

Abbott was not the proximate and/or competent producing cause of such alleged injuries and damages.

8. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses may have been caused, may have been solely caused, may be barred, and/or may be limited in whole or in part by the contributory negligence or comparative fault and/or comparative negligence of Plaintiff.

9. In the alternative, without waiving its denial of liability to Plaintiff, Abbott states that, assuming that 100% represents the total combined fault of the parties to this action, the fault on the part of Plaintiff was more than 50% of the total proximate cause of the alleged injuries and, therefore, there is no liability on the part of Abbott. In the alternative, in the event that it is found that fault on the part of Plaintiff is less than 50% of the proximate cause of the alleged injury, then the amount of the verdict awarded to Plaintiff must be reduced in accordance with the percentage of that fault.

10. If Plaintiff has sustained injuries or losses, as alleged in the Complaint, Plaintiff's claims regarding such injuries or losses may be barred or reduced by Plaintiff's knowingly, voluntarily, and/or willfully assuming the risk of any injury as the result of the consumption of, administration of, or exposure to the product at issue or any medicine or pharmaceutical preparation manufactured or distributed by another manufacturer.

11. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Abbott and over whom Abbott had no control and for whom Abbott may not be held accountable.

12. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by circumstances, events, or persons over whom Abbott had no authority or control and for which Abbott is not answerable in damages to Plaintiff.

13. To the extent Plaintiff's claims were caused by the actions, omissions, or products of persons or entities over whom Abbott has no dominion, authority, or control, Abbott is entitled to have its liability to the Plaintiff, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

14. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse or abuse of the product at issue after it left the control of Abbott.

15. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were the result of unavoidable circumstances that could not have been prevented by any person, including Abbott.

16. Abbott denies any liability, but if Abbott is ultimately found liable to Plaintiff, then Abbott shall only be liable for its equitable share of Plaintiff's recovery since any such liability would be insufficient to impose joint liability.

17. If Plaintiff recovers from Abbott, Abbott is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence of fault proximately caused or contributed to cause Plaintiff's alleged damages.

18. Any verdict of judgment rendered against Abbott must be reduced by the comparative fault of other persons or entities.

19. Any verdict of judgment rendered against Abbott must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part for any past or future loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

20. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by the off-label use of the product at issue that Abbott did not proscribe and for which Abbott is not legally responsible.

21. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated physical, physiological, medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions, or natural courses of conditions for which Abbott is not legally responsible.

22. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

23. Plaintiff did not detrimentally rely on any labeling, warnings, or information concerning Prevacid®.

24. Any warranties made by Abbott to Plaintiff were disclaimed.

25. To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are barred for lack of timely notice of any breach or alleged failure.

26. Abbott did not sell or distribute Prevacid® directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims are therefore barred by lack of privity.

27. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

28. Any claim for breach of express warranty must fail because Plaintiff failed to allege any representations about the product at issue giving rise to an express warranty.

29. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Abbott in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of Prevacid®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

30. Plaintiff cannot establish that any reasonable alternative design would have rendered the product at issue safer overall, and that the failure to adopt a reasonable alternative design rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

31. Plaintiff cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risks of harm posed by the product at issue would have rendered the product safer overall, and that the failure to provide such alternative instructions or warnings rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

32. Each and every claim alleged or raised in the Complaint is barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

33. Each and every claim alleged or raised in the Complaint is barred in whole or in part because legally adequate "directions or warnings" were provided as to the use of the product at issue and any other medicine or pharmaceutical preparation to which Plaintiff attributes Plaintiff's alleged damages within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

34. Each and every claim alleged or raised in the Complaint is barred by Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

35. Each and every claim alleged or raised in the Complaint is barred by comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

36. Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of the product at issue.

37. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government, and/or the *Noerr-Pennington* doctrine.

38. Each and every claim alleged or raised in the Complaint is barred in whole or in part by Plaintiff's failure to mitigate alleged damages.

39. Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate their claims to negligence.

40. All activities of Abbott as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to any alleged misrepresentations or omissions are barred.

41. Each and every claim alleged or raised in the Complaint is barred because, if the product at issue was unsafe, which Abbott denies, then it was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk, given the scientific knowledge available when the product was marketed.

42. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical product at issue provide net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

43. Plaintiff, or Plaintiff's physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of Prevacid® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings.

44. Plaintiff's claims are barred because Prevacid® was consistent with and exceeded consumer expectations.

45. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

46. Abbott had a good faith belief in the lawfulness of its actions.

47. The advertisements and labeling with respect to the product at issue were not false or misleading and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution and the state Constitution.

48. The public interest in the benefit and availability of the product at issue precludes liability for risks, if any, resulting from any activities undertaken by Abbott, that were unavoidable, given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product at issue, then such risk, if any, is outweighed by the benefit of the product.

49. Plaintiff's failure to warn claim is barred given that Abbott had no duty to warn of risks of which Abbott neither knew nor should have known at the time Prevacid® was designed, distributed, and manufactured.

50. At all relevant times, Prevacid® was manufactured and distributed in a reasonable and prudent manner, based upon available medical and scientific knowledge, and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

51. To the extent there were any risks associated with the use of Prevacid® that Abbott knew or should have known and that gave rise to a duty to warn, which Abbott denies, Abbott at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

52. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

53. Each and every claim alleged or raised in the Complaint may be barred because Plaintiff has failed to comply with the conditions precedent or subsequent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

54. Each and every claim alleged or raised in the Complaint may be barred in whole or in part by the doctrine of informed consent.

55. Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources.

56. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

57. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Abbott, if any, should be reduced accordingly.

58. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or release of claims.

59. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

60. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, or suppression.

61. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Abbott and all of its activities with respect to the product at issue have been and are conducted under the supervision of the FDA.

62. Each and every claim alleged or raised in the Complaint and based on allegedly inadequate warnings is barred even if Abbott failed to provide adequate warnings with respect to known or potential dangers or risks associated with the use of the product, because physicians prescribing the product at issue either knew or should have known of the potential or known dangers or risks,

and there is no duty to warn members of a profession against dangers known or that should be known to members of the profession.

63. Any injuries or damages Plaintiff may have sustained may have been caused by a substantial change in the product at issue after leaving the possession, custody, and control of Abbott, if applicable.

64. The common law claims and theories of liability set forth in the Complaint are barred by the doctrine of federal preemption. Abbott's conduct conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, each and every claim alleged or raised in the Complaint is barred in whole or in part under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

65. The New Drug Application for Prevacid® was approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such statutes and regulations by Abbott, as applicable, demonstrates that Prevacid® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiff's claims against Abbott. Compliance with any applicable statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of Prevacid®, and that it was neither defective nor unreasonably dangerous.

66. Plaintiff's claims are barred because Prevacid® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiff's recovery.

67. The warnings and instructions accompanying Prevacid® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

68. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding Prevacid® and other drugs in its class.

69. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

70. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

71. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid in the United States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

72. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

73. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

74. All labeling for Prevacid® has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder. Plaintiff's claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent

Plaintiff asserts that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ____ (2019). Plaintiff's claims also are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives. Additionally, Plaintiff's design defect claims are barred by the doctrine of federal preemption under *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

75. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

76. Plaintiff's attempt to collect damages from Abbott based on Plaintiff's alleged injuries caused by a product that Abbott may not have manufactured or sold violates Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the applicable states' Constitutions.

77. Plaintiff did not suffer any actual injury, loss, or damages because of Plaintiff's alleged use of Prevacid®.

78. Plaintiff's claims may be barred, in whole or in part, because Abbott did not design, manufacture, promote, or sell the products which form the basis of Plaintiff's claims.

79. All or part of the injuries, damages, and/or losses, if any, sustained by Plaintiff, if proven, were caused in whole or in part by the acts or omissions of others for whose conduct Abbott is not responsible and/or resulted from conditions or events unrelated to any conduct by Abbott.

80. Some or all of Plaintiff's claims and/or damages, if any, may be barred, limited, or offset by the law of other states that may govern under this jurisdiction's choice of law provisions and resulting application of law from other jurisdictions. These may include, without limitation, another state's product liability statute, its applicable statute of limitations, its modified comparative fault doctrine, and limitations on the award of noneconomic and punitive damages.

81. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

82. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages ("punitive damages") for the conduct that allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Abbott's rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution(s).

83. Any claim by Plaintiff for punitive damages is in contravention of Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; similar provisions in the states of Plaintiff's citizenship; and/or the common law and public policies of such states.

84. To the extent that Plaintiff seeks punitive damages, said claim is unconstitutionally vague and/or overly broad because of the lack of clear standards. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on

conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitutions, and applicable state common law and public policies.

85. Plaintiff's claim for punitive damages against Abbott cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Abbott; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards. Any such verdict would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under applicable state common law and public policies.

86. Unless Abbott's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to

the United States Constitution and the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

87. To the extent that Plaintiff seeks punitive damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and subsequent cases, including *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

88. To the extent that Plaintiff seeks punitive damages, any award against Abbott on any grounds other than its conduct with regard to the product Plaintiff used would be improper under applicable constitutional principles.

89. No act or omission of Abbott was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiff or with conscious disregard and indifference to the rights, safety and welfare of Plaintiff, and, therefore, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

90. To the extent that Plaintiff seeks punitive damages, such claim is barred because the product at issue, and its labeling, was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

91. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Abbott and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing

punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the applicable state constitutions.

92. With respect to Plaintiff's demand for punitive or exemplary damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and the applicable state law.

93. Plaintiff's Complaint seeks damages in excess of those permitted by law. Abbott asserts any statutory or judicial protection from punitive or exemplary damages which is available under the applicable law, including applicable statutory or other caps or limitations on the recovery or punitive or exemplary damages, and any award of punitive or exemplary damages is barred.

94. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, because Plaintiff may lack capacity or standing to bring the claims alleged.

95. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Abbott to determine all of its legal, contractual, and equitable rights, Abbott reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent defenses ascertained through further investigation and discovery.

96. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

97. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid in the United

States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

98. Discovery or investigation may reveal that some or all of the claims alleged by Plaintiff are barred by the doctrines of accord and satisfaction.

99. Abbott is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

100. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and Abbott hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

101. Abbott hereby pleads all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22-2307.29.

102. Plaintiff's claims are barred because Prevacid® is an "ethical drug" as defined by Ohio Rev. Code Ann. § 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.

103. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in O.R.C. §§ 2315.22, *et seq.* and 2315.32-2315.36.

104. Plaintiff's recovery as against Abbott should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.

105. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.

106. Plaintiff's right to recover damages, if any, is statutorily limited by Ohio's wrongful death statute, Ohio Rev. Code Ann. §§ 2125.01 through 2125.04.

107. Plaintiff's claims for punitive or exemplary damages as set forth in the complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).

108. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

109. Ohio's Consumer Sales Practices Act, Ohio Rev. C. §1345.12(C), specifically precludes claims for personal injury or death.

110. Plaintiff fails to state a claim for relief under Ohio Rev. Code Ann. §§ 1345.01, *et seq.*

111. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

112. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

113. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code § 2307.711.

114. All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct Abbott had no reason to anticipate and for whose conduct Abbott is not and were not responsible. Ohio Revised Code § 2307.22, *et seq.*

115. The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code § 2307.23.

116. One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Revised Code §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, *et al.*

117. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(D) because adequate warning and instruction were provided under Ohio Revised Code § 2307.76 concerning any unavoidably unsafe aspects of the product.

118. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

119. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Revised Code § 2307.75(F).

120. Plaintiff's inadequate warning claims are barred under Ohio Revised Code § 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

121. Abbott adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

122. Abbott is entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of applicable state and federal law.

JURY DEMAND

Abbott hereby demands a trial by jury by the maximum number of jurors permitted by law

on all issues so triable.

PRAYER

WHEREFORE, having answered, Abbott requests that this Court enter judgment in its favor and against Plaintiff on all counts and allegations of the Complaint and that the Court award Abbott its costs and such other relief as it deems just and proper.

DATED: July 5, 2019

Respectfully submitted,

By: /s/ Gregory Brunton

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***Attorneys for Defendant Abbott
Laboratories***

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served on July 5, 2019 via electronic mail on the following:

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/s/ Gregory D. Brunton

Gregory Brunton (0061722)

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA A. BEHYMER,

Plaintiff,

v.

ABBOT LABORATORIES, *et al.*,

Defendants.

Case No. A 1902638

Judge Charles J. Kubicki, Jr.

**NOVARTIS DEFENDANTS' MOTION
FOR EXTENSION OF TIME TO MOVE,
PLEAD, OR RESPOND TO
PLAINTIFF'S COMPLAINT**

Defendants Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes For Biomedical Research, Inc., and Novartis Vaccines And Diagnostics, Inc. (collectively, the “Novartis Defendants”), by and through undersigned counsel, specially appear and hereby move for an extension of time to move, plead, or otherwise respond to Plaintiff’s Complaint.

This case is one of 76 cases filed on May 30 and 31, 2019, against various defendants, including the Novartis Defendants, alleging injuries sustained from using various proton pump inhibitor (“PPI”) medications. Each of these complaints runs in excess of 70 pages and contains between 350 to over 500 paragraphs of allegations. The Novartis Defendants received service of Plaintiff’s Complaint on or around June 11, 2019¹, making the Novartis Defendants’ deadline to move, plead, or otherwise respond to Plaintiff’s Complaint July 9, 2019.

The Novartis Defendants’ have been in negotiations with national plaintiffs’ counsel seeking the voluntary dismissal of the claims against them, as the Novartis Defendants are not properly named entities because they are not responsible for any medication at issue in this

¹ Defendant Novartis Corp., a New York corporation, has not been properly served, as the summons and comp were not mailed to its principle place of business in New Jersey.



litigation. The Novartis Defendants seek additional time to pursue those discussions now that plaintiffs have instituted actions against them in this venue, and potentially avoid the need for motions to dismiss.

In light of this, counsel contacted Plaintiffs' Ohio counsel to request a stipulation of extension of time to move or plead, consistent with this Court's Local Rule 12. However, Plaintiffs' Ohio counsel advised that Plaintiffs' out-of-state lead counsel would not stipulate to any extensions of time whatsoever.

Accordingly, the Novartis Defendants respectfully move for a 28-day extension of time until August 6, 2019, to move, plead, or otherwise respond to Plaintiff's Complaint in this case. A proposed order granting this motion will be submitted separately for the Court's convenience.

Respectfully submitted,

/s/ Joyce D. Edelman

Joyce D. Edelman (0023111), Trial Attorney

Ryan L. Graham (0093826)

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CERTIFICATE OF SERVICE

I certify that pursuant to Rule 5(B)(3) of the Ohio Rules of Civil Procedure, I electronically filed the foregoing on July 5, 2019 using the Clerk's e-filing system, which system will send electronic notification constituting service on the following counsel who have appeared in the matter:

/s/ Joyce D. Edelman
Joyce D. Edelman

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA A. BEHYMER,	:	Case No.: A 1902638
	:	
Plaintiff,	:	Judge Charles Kubicki
	:	
vs.	:	ANSWER AND AFFIRMATIVE
	:	DEFENSES OF DEFENDANTS
	:	GLAXOSMITHKLINE CONSUMER
ABBOTT LABORATORIES, <i>et al.</i> ,	:	HEALTHCARE HOLDINGS (US), LLC;
	:	GLAXOSMITHKLINE CONSUMER
Defendants.	:	HEALTHCARE HOLDINGS (US) IP,
	:	LLC; AND NOVARTIS CONSUMER
	:	HEALTH, INC., TO PLAINTIFFS'
	:	COMPLAINT
	:	
	:	(Jury Demand Endorsed Hereon)

Defendants GlaxoSmithKline Consumer Healthcare Holdings (US), LLC; GlaxoSmithKline Consumer Healthcare Holdings (US) IP, LLC¹; and Novartis Consumer Health, Inc. (collectively the "GSK Defendants), by and through undersigned counsel, hereby answer Plaintiff Teresa Behymer's ("Plaintiff") Complaint as follows:

REGARDING "NATURE OF THE ACTION"

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts to date,

¹ The GSK Defendants note that, though one paragraph of the Complaint (§ 46) refers to GlaxoSmithKline Consumer Healthcare Holdings (US) IP, LLC, as a defendant in this action, this is neither named in the caption of the Complaint, nor is it listed in the preamble. However, out of abundance of caution, the GSK Defendants are answering on behalf of GlaxoSmithKline Consumer Healthcare Holdings (US) IP, LLC.



regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

ANSWER: Some of the allegations contained in Paragraph 1 of Plaintiff's Complaint are directed to a party or entity other than the GSK Defendants and constitute legal conclusions, and accordingly, no response is required. To the extent the allegations are directed to the GSK Defendants, and to the extent a response is required, Defendants GlaxoSmithKline Consumer Healthcare Holdings (US), LLC, and GlaxoSmithKline Consumer Healthcare Holding (US) IP, LLC, deny the allegations contained in Paragraph 1. Novartis Consumer Health, Inc., now known as GSK Consumer Health, Inc., admits only that it currently markets the proton pump inhibitor ("PPI") Prevacid®24HR (hereinafter referred to as "Prevacid24HR").

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

ANSWER: The allegations in Paragraph 2 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

ANSWER: The allegations contained in Paragraph 3 of Plaintiff's Complaint state legal conclusions and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching,

developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to, Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

ANSWER: Some of the allegations contained in Paragraph 4 of Plaintiff's Complaint are directed to a party or entity other than the GSK Defendants and constitute legal conclusions, and accordingly, no response is required. To the extent the allegations are directed to the GSK Defendants, and to the extent a response is required, Defendants GlaxoSmithKline Consumer Healthcare Holdings (US), LLC, and GlaxoSmithKline Consumer Healthcare Holding (US) IP, LLC, deny the allegations contained in Paragraph 4. Novartis Consumer Health, Inc., now known as GSK Consumer Health, Inc., admits only that it currently markets Prevacid24HR.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease ("GERD") and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

ANSWER: The GSK Defendants admit that PPIs are used to treat peptic ulcers. After reasonable investigation, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 5 of Plaintiff's Complaint and therefore deny the same.

REGARDING "PARTIES, JURISDICTION & VENUE"

6. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court. The amount in controversy exceeds TWENTY- FIVE THOUSAND DOLLARS (\$25,000.00), exclusive of interest and costs, the jurisdictional minimum of this Court.

ANSWER: The allegations contained in Paragraph 6 of Plaintiff's Complaint are not direct towards the GSK defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

7. Plaintiff, Teresa A. Behymer, resides in Westchester, Ohio and resided in Westchester, Ohio at all times relevant.

ANSWER: The allegations contained in Paragraph 7 of Plaintiff's Complaint are not directed towards the GSK defendants and, accordingly, no response is required. However, to the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 7 of Plaintiff's Complaint and therefore deny the same.

a. Plaintiff, Teresa A. Behymer ingested the following PPI products sold by the Defendants from at least approximately January 2014 to December 2018:, Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

ANSWER: The allegations contained in Paragraph 7a are directed at products other than Prevacid24HR and, accordingly, no response is required. To the extent the allegations contained in Paragraph 7a are directed towards the GSK Defendants, they lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 7a of Plaintiff's Complaint and therefore deny the same.

b. As a direct and proximate result of Plaintiff's use of the PPI(s), Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix, Plaintiff has suffered and was treated for, Chronic Kidney Disease ("CKD"), in approximately August 2016 with related sequelae.

ANSWER: The allegations contained in Paragraph 7b are directed at products other than Prevacid24HR, defendants other than the GSK Defendants, and constitute legal conclusions; therefore, no response is required. To the extent the allegations contained in Paragraph 7b are directed towards the GSK Defendants and to the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 7b of Plaintiff's Complaint.

REGARDING "DEFENDANTS"

8. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

ANSWER: The allegations contained in Paragraph 8 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

9. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

ANSWER: The allegations contained in Paragraph 9 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

10. Defendant Abbott manufactures and markets Prevacid in the United States.

ANSWER: The allegations contained in Paragraph 10 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

11. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 11 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

12. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 12 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

13. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

ANSWER: The allegations contained in Paragraph 13 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

14. Defendant AstraZeneca Pharmaceuticals LP (“AZ Pharm”) is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

ANSWER: The allegations contained in Paragraph 14 of Plaintiff’s Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

15. Defendant AstraZeneca LP (“AZ LP”) is, and at all times relevant to this action, has been a limited partnership organized under the laws of Delaware having a principal place of business in Delaware, whose ultimate parent company is AstraZeneca PLC.

ANSWER: The allegations contained in Paragraph 15 of Plaintiff’s Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

16. Defendants AZ Pharm and AZ LP are referred to collectively herein as “AZ Defendants.”

ANSWER: The allegations contained in Paragraph 16 of Plaintiff’s Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

17. Each of the AZ Defendants was the agent and employee of the other AZ Defendants and, in doing the things alleged, was acting within the course and scope of such

agency and employment and with the other AZ Defendants' actual and implied permission, consent, authorization and approval.

ANSWER: The allegations contained in Paragraph 17 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

18. The AZ Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

ANSWER: The allegations contained in Paragraph 18 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

19. As a part of their business and at all relevant times, the AZ Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

ANSWER: The allegations contained in Paragraph 19 of Plaintiff's Complaint are not directed towards the GSK defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

20. In 1982, the AZ Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

ANSWER: The allegations contained in Paragraph 20 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

21. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

ANSWER: The allegations contained in Paragraph 21 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

22. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

ANSWER: The allegations contained in Paragraph 22 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

23. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec which, by the year 2000, was the most widely prescribed drug in the world.

ANSWER: The allegations contained in Paragraph 23 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

24. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

ANSWER: The allegations contained in Paragraph 24 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

25. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

ANSWER: The allegations contained in Paragraph 25 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

26. In an agreement reached in December 1997, the AstraZeneca Defendants entered into a co-promotion agreement with the Procter & Gamble Defendants granting the Procter & Gamble Defendants the right to market Prilosec.

ANSWER: The allegations contained in Paragraph 26 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

27. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec and the Procter & Gamble Defendants market and sell Prilosec.

ANSWER: The allegations contained in Paragraph 27 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

28. Pursuant to the terms of the co-promotion agreement, the Procter & Gamble Defendants marketed and sold Prilosec from at least December 8, 1997 through January 12, 2001.

ANSWER: The allegations contained in Paragraph 28 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

29. In 2006, the FDA approved New Drug Application ("NDA") 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

ANSWER: The allegations contained in Paragraph 29 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

30. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

ANSWER: The allegations contained in Paragraph 30 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

31. Defendant AZ LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

ANSWER: The allegations contained in Paragraph 31 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

32. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

ANSWER: The allegations contained in Paragraph 32 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

33. In anticipation of the expiration of the patent for prescription Prilosec, the AZ Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

ANSWER: The allegations contained in Paragraph 33 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

34. In December 1999, Defendant AZ Pharm submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

ANSWER: The allegations contained in Paragraph 34 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

35. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

ANSWER: The allegations contained in Paragraph 35 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

36. Defendant AZ Pharm is also the holder of approved NDAs 021957 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

ANSWER: The allegations contained in Paragraph 36 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

37. The AZ Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

ANSWER: The allegations contained in Paragraph 37 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

38. In 2003, the AZ Defendants spent \$260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

ANSWER: The allegations contained in Paragraph 38 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

39. The AZ Defendants have transacted and conducted business related to PPI products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 39 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

40. The AZ Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was \$2.7 billion and world-wide was \$3.9 billion.

ANSWER: The allegations contained in Paragraph 40 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

41. The AZ Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPIs.

ANSWER: The allegations contained in Paragraph 41 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

42. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 42 of Plaintiff's Complaint, as phrased. The GSK Defendants admit that GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is a Delaware private limited liability company that conducts business at 184 Liberty Corner Road, Warren, NJ 07059.

43. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, pursuant to an agreement with the Novartis Defendants, obtained the rights to market and sell the over-the-counter medication Prevacid 24Hr.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 43 of Plaintiff's Complaint, as phrased. However, the GSK Defendants state in response to the allegations contained in Paragraph 43 that Novartis Consumer Health, Inc., now known as GSK Consumer Health, Inc., admits only that it currently markets Prevacid24HR.

44. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, in collaboration and amongst themselves, designed and developed Prevacid 24HR.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 44 of Plaintiff's Complaint.

45. As a part of their business and at all relevant times, Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR products.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 45 of Plaintiff's Complaint.

46. Defendant GSK Consumer Healthcare (US) IP LLC is the holder of approved NDA 022327 for Prevacid 24HR.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC manufacture and market Prevacid 24HR in the United States.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 47 of Plaintiff's Complaint.

48. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 48 of Plaintiff's Complaint constitute legal conclusions to which no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 48.

49. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 49 of Plaintiff's Complaint constitute legal conclusions to which no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 49.

50. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

ANSWER: The allegations contained in Paragraph 50 of Plaintiff's Complaint constitute legal conclusions to which no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 50.

51. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter "Defendant Merck") is and, all times relevant to this action, has been a New Jersey

corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

ANSWER: The allegations contained in Paragraph 51 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

52. In 1982, Defendant Merck entered into an agreement with the AZ Defendants, under the terms of which Defendant Merck developed and marketed the AZ Defendants' products, including Nexium and Prilosec products, under a royalty-bearing license.

ANSWER: The allegations contained in Paragraph 52 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

53. In 1993, Merck's total sales of the AstraZeneca Defendants' products reached a level that triggered the first step in the establishment of a joint venture business (the "Joint Venture") in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

ANSWER: The allegations contained in Paragraph 53 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

54. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

ANSWER: The allegations contained in Paragraph 54 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

55. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

ANSWER: The allegations contained in Paragraph 55 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

56. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

ANSWER: The allegations contained in Paragraph 56 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

57. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion,

marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

ANSWER: The allegations contained in Paragraph 57 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

58. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

ANSWER: The allegations contained in Paragraph 58 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

59. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

ANSWER: The allegations contained in Paragraph 59 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

60. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

ANSWER: The allegations contained in Paragraph 60 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

61. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

ANSWER: The allegations contained in Paragraph 61 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

62. Defendant Merck manufactures and markets Nexium products in the United States.

ANSWER: The allegations contained in Paragraph 62 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

63. Defendant Merck manufactures and markets Prilosec products in the United States.

ANSWER: The allegations contained in Paragraph 63 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

64. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 64 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

65. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 65 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

66. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: The allegations contained in Paragraph 66 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

67. Defendant Novartis Corporation is and, at all times relevant to this action, has been a New York corporation having a principal place of business in East Hanover, NJ.

ANSWER: The allegations contained in Paragraph 67 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 67 of Plaintiff's Complaint and therefore deny the same.

68. Defendant Novartis Pharmaceuticals Corporation is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, NJ 07936.

ANSWER: The allegations contained in Paragraph 68 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 68 of Plaintiff's Complaint and therefore deny the same.

69. Defendant Novartis Institutes for Biomedical Research, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business at 250 Massachusetts Avenue, Cambridge, MA 02139.

ANSWER: The allegations contained in Paragraph 69 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 69 of Plaintiff's Complaint and therefore deny the same.

70. Defendant Novartis Vaccines and Diagnostics, Inc. is and, at all times relevant to this action, has been a Delaware corporation with a principal place of business in East Hanover, NJ.

ANSWER: The allegations contained in Paragraph 70 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 70 of Plaintiff's Complaint and therefore deny the same.

71. Defendant Novartis Corporation is the parent/holding company of Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

ANSWER: The allegations contained in Paragraph 71 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations are directed towards Novartis Consumer Health, Inc., the GSK Defendants deny that Novartis Corporation is the parent/holding company of Novartis Consumer Health, Inc.

72. At all relevant times, Defendant Novartis Corporation has exercised and exercises dominion and control over Defendants Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc.

ANSWER: The allegations contained in Paragraph 72 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 72 are directed to Novartis Consumer Health, Inc., the GSK Defendants deny the allegations.

73. Defendants Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research, Inc., and Novartis Vaccines and Diagnostics, Inc. are herein referred to collectively as “Novartis Defendants.”

ANSWER: The GSK Defendants state that Paragraph 73 of Plaintiff’s Complaint contains statements to which no responses is required and, therefore, none is made.

74. Each of the Novartis Defendants was the agent and employee of the other Novartis Defendants, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Novartis Defendants’ actual and implied permission, consent, authorization and approval.

ANSWER: The allegations contained in Paragraph 74 of Plaintiff’s Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 74 are directed to Novartis Consumer Health, Inc., the GSK Defendants deny the allegations.

75. In 2005, the Novartis Defendants obtained the rights to market the over-the-counter version of Prevacid, Prevacid 24HR.

ANSWER: The allegations contained in Paragraph 75 of Plaintiff’s Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 75 are directed to Novartis Consumer Health, Inc., the GSK Defendants, on information and belief, deny the allegations.

76. As part of their business and at all relevant times, the Novartis Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR.

ANSWER: The allegations contained in Paragraph 76 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 76 are directed to Novartis Consumer Health, Inc., the GSK Defendants state that Novartis Consumer Health, Inc., n/k/a GSK Consumer Health Inc., admits only that it currently markets Prevacid24HR. The GSK Defendants lack sufficient knowledge and information to form a belief regarding the truth of the remaining allegations contained in Paragraph 76 of Plaintiff's Complaint and therefore deny the same.

77. The Novartis Defendants, in collaboration amongst themselves, designed and developed the Prevacid 24 HR.

ANSWER: The allegations contained in Paragraph 77 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 77 are directed to Novartis Consumer Health, Inc., the GSK Defendants state that they lack sufficient knowledge and information to form a belief regarding the truth of the remaining allegations contained in Paragraph 77 of Plaintiff's Complaint and therefore deny the same.

78. Defendant Novartis Pharmaceuticals Corporation has been the holder of approved NDA 022327 for Prevacid 24HR.

ANSWER: The allegations contained in Paragraph 78 of Plaintiff's Complaint are not directed towards the GSK Defendants and also constitute legal conclusions and, therefore, no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 78 of Plaintiff's Complaint.

79. The Novartis Defendants manufacture and market Prevacid 24HR in the United States.

ANSWER: The allegations contained in Paragraph 79 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 79 are directed to Novartis Consumer Health, Inc., the GSK Defendants state that Novartis Consumer Health, Inc., n/k/a GSK Consumer Health Inc., admits only that it currently markets Prevacid24HR. The GSK Defendants deny the remaining allegations in Paragraph 79 of Plaintiff's Complaint.

80. The Novartis Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 80 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 80 are directed to Novartis Consumer Health, Inc., the GSK Defendants deny the allegations contained in Paragraph 80 of Plaintiff's Complaint.

81. The Novartis Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 81 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 81 are directed to Novartis Consumer Health, Inc., the GSK Defendants deny the allegations contained in Paragraph 81 of Plaintiff's Complaint.

82. The Novartis Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid 24HR.

ANSWER: The allegations contained in Paragraph 82 of Plaintiff's Complaint are not directed towards the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required and to the extent the allegations in Paragraph 82 are directed to Novartis Consumer Health, Inc., the GSK Defendants deny the allegations contained in Paragraph 82 of Plaintiff's Complaint.

83. Defendant Pfizer Inc. is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 235 East 42nd Street, New York, NY 10017.

ANSWER: The allegations contained in Paragraph 83 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

84. As a part of their business and at all relevant times, Defendant Pfizer Inc. has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of the drugs Protonix (pantoprazole) and Nexium 24HR.

ANSWER: The allegations contained in Paragraph 84 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

85. In or about 2012, Defendant Pfizer Inc. entered into a marketing agreement with the AstraZeneca Defendants whereby Defendant Pfizer Inc. acquired the rights to market Nexium 24HR products.

ANSWER: The allegations contained in Paragraph 85 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

86. On or about March 28, 2014, Defendant Pfizer Inc., in collaboration with and pursuant to its marketing agreement with the AstraZeneca Defendants, was granted FDA approval to market Nexium 24HR products.

ANSWER: The allegations contained in Paragraph 86 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

87. Defendant Pfizer Inc. makes Nexium 24HR available for purchase in the United States in and around 2014 and continues to manufacture and market Nexium 24HR in the United States.

ANSWER: The allegations contained in Paragraph 87 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

88. Defendant Pfizer Inc. manufactures and markets Protonix in the United States.

ANSWER: The allegations contained in Paragraph 88 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

89. Defendant Pfizer Inc. has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 89 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

90. Defendant Pfizer Inc. has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 90 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

91. Defendant Pfizer Inc. has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: The allegations contained in Paragraph 91 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

92. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

ANSWER: The allegations contained in Paragraph 92 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

93. Defendant The Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

ANSWER: The allegations contained in Paragraph 93 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

94. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests of Defendant The Procter & Gamble Manufacturing Company.

ANSWER: The allegations contained in Paragraph 94 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

95. Defendant The Procter & Gamble Company and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

ANSWER: The GSK Defendants state that Paragraph 95 of Plaintiff’s Complaint contains statements to which no responses is required and, therefore, none is made.

96. Each of the Procter & Gamble Defendants was the agent and employee of the Other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant’s actual and implied permission, consent, authorization and approval.

ANSWER: The allegations contained in Paragraph 96 of Plaintiff’s Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

97. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

ANSWER: The allegations contained in Paragraph 97 of Plaintiff’s Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

98. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

ANSWER: The allegations contained in Paragraph 98 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

99. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

ANSWER: The allegations contained in Paragraph 99 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

100. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

ANSWER: The allegations contained in Paragraph 100 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

101. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

ANSWER: The allegations contained in Paragraph 101 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

102. The Procter & Gamble Defendants made Prilosec OTC available for purchase in the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

ANSWER: The allegations contained in Paragraph 102 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

103. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 103 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

104. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 104 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

105. The Procter & Gamble Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and

derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prilosec OTC.

ANSWER: The allegations contained in Paragraph 105 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

106. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: The allegations contained in Paragraph 106 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

107. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: The allegations contained in Paragraph 107 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

108. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

ANSWER: The allegations contained in Paragraph 108 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

109. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: The allegations contained in Paragraph 109 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

110. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

ANSWER: The allegations contained in Paragraph 110 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

111. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: The allegations contained in Paragraph 111 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

112. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: The allegations contained in Paragraph 112 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

113. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as "Takeda Defendants."

ANSWER: The GSK Defendants state that Paragraph 113 of Plaintiff's Complaint contains statements to which no responses is required and, therefore, none is made.

114. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants' actual and implied permission, consent, authorization and approval.

ANSWER: The allegations contained in Paragraph 114 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

115. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid, Prevacid 24HR and Protonix products.

ANSWER: The allegations contained in Paragraph 115 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations contained in Paragraph 115 and, therefore, deny the same.

116. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid, Prevacid 24HR and Protonix products.

ANSWER: The allegations contained in Paragraph 116 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent a response is required, the GSK Defendants lack sufficient knowledge or information to form a belief regarding the truth of the allegations contained in Paragraph 116 and, therefore, deny the same.

117. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

ANSWER: The allegations contained in Paragraph 117 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

118. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

ANSWER: The allegations contained in Paragraph 118 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

119. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

ANSWER: The allegations contained in Paragraph 119 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 119.

120. The Takeda Defendants manufacture and market each of these Protonix formulations in the United States.

ANSWER: The allegations contained in Paragraph 120 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

121. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 121 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the

extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

122. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: The allegations contained in Paragraph 122 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

123. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: The allegations contained in Paragraph 123 of Plaintiff's Complaint are not directed towards the GSK Defendants and, accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly on the GSK Defendants, those allegations are denied.

124. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

ANSWER: The allegations contained in Paragraph 124 of Plaintiff's Complaint are directed towards entities other than the GSK Defendants and also state legal conclusions; therefore, no

response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 124 of Plaintiff's Complaint.

125. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

ANSWER: The allegations contained in Paragraph 125 of Plaintiff's Complaint are directed towards entities other than the GSK Defendants and also state legal conclusions; therefore, no response is required. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

REGARDING "FACTUAL ALLEGATIONS"

Regarding "A. General Background: Proton Pump Inhibitors"

126. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

ANSWER: The allegations contained in Paragraph 126 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent they purport to cast liability, either directly or indirectly, on the GSK Defendants, those allegations are denied. The GSK Defendants admit that Prevacid24HR is indicated for treatment of frequent heartburn (occurs two or more days a week).

127. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

ANSWER: The allegations contained in Paragraph 127 of Plaintiff's Complaint are directed towards products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent they are directed at Prevacid24HR, the GSK Defendants admit that Prevacid24HR is a proton pump inhibitor that works by blocking the gastric H,K-ATPase of the parietal cell, inhibiting gastric acid secretion.

128. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

ANSWER: The allegations contained in Paragraph 128 of Plaintiff's Complaint are directed towards products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent a response is required, the GSK Defendants deny these allegations.

129. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

ANSWER: The allegations contained in Paragraph 129 of Plaintiff's Complaint are directed towards products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent a response is required, the GSK Defendants deny these allegations.

130. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

ANSWER: The allegations contained in Paragraph 130 of Plaintiff's Complaint are directed towards products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent a response is required, the GSK Defendants deny these allegations.

131. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

ANSWER: The allegations contained in Paragraph 131 of Plaintiff's Complaint are directed towards products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent a response is required, the GSK Defendants deny these allegations.

Regarding "B. PPI Products Cause Severe Kidney Injuries"

132. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

ANSWER: In response to the allegations contained in Paragraph 132 of Plaintiff's Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 132 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

133. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse

reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

ANSWER: The allegations contained in Paragraph 133 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent they are direct at Prevacid24HR, the GSK Defendants deny the allegations contained in Paragraph 133.

Regarding "i. PPI-Induced Acute Interstitial Nephritis ("AIN")"

134. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

ANSWER: The allegations contained in Paragraph 134 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent they are direct at Prevacid24HR, the GSK Defendants deny the allegations contained in Paragraph 134.

135. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

ANSWER: In response to the allegations contained in Paragraph 135 of Plaintiff's Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 135 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

136. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, “Systematic review: proton pump inhibitor-associated acute interstitial nephritis.” The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

ANSWER: In response to the allegations contained in Paragraph 136 of Plaintiff’s Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 136 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

137. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, “where PPI-induced AIN is disproportionately present in the database.” Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

ANSWER: In response to the allegations contained in Paragraph 137 of Plaintiff’s Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 137 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

138. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

ANSWER: In response to the allegations contained in Paragraph 138 of Plaintiff's Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 138 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

139. According to the Public Citizen petition, at the time of the filing there was "no detailed risk information on any PPI for this adverse effect."

ANSWER: In response to the allegations contained in Paragraph 139 of Plaintiff's Complaint, the GSK Defendants respond that the publication speaks for itself. Furthermore, the allegations contained in Paragraph 139 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

140. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

ANSWER: The allegations contained in Paragraph 140 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK

Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations.

141. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

ANSWER: The allegations contained in Paragraph 141 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations.

142. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

ANSWER: The allegations contained in Paragraph 142 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations.

143. To this date, Defendants’ over-the-counter PPI Products do not include a warning or any risk information about AIN.

ANSWER: The allegations contained in Paragraph 143 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants state that the Prevacid24HR label speaks for itself and, to the extent that the allegations purport to cast liability on the GSK Defendants, either directly or indirectly, those allegations are denied.

144. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

ANSWER: The allegations contained in Paragraph 144 of Plaintiff's Complaint constitute legal conclusions to which no response is required. Further, the allegations contained in Paragraph 144 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Finally, to the extent that Paragraph 144 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. However, to the extent a response is required, the GSK Defendants deny these allegations.

145. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the-counter PPI Products.

ANSWER: The allegations contained in Paragraph 145 of Plaintiff's Complaint constitute legal conclusions to which no response is required. Further, the allegations contained in Paragraph 145 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed at Prevacid24HR, and a response is required, the GSK Defendants deny these allegations.

146. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

ANSWER: The allegations contained in Paragraph 146 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Further, to the extent that Paragraph 146 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent that the allegations are directed at Prevacid24HR, the GSK Defendants deny the allegations contained in Paragraph 146.

147. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

ANSWER: To the extent Paragraph 147 of Plaintiff's Complaint calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 147.

148. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, Proton Pump Inhibitors and CKD, 27 J. AM. SOC. NEPHROL. 2926 (2016).

ANSWER: The allegations contained in Paragraph 148 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed at Prevacid24HR, the GSK Defendants deny the allegations contained in Paragraph 148 and state that the publications speak for themselves.

149. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

ANSWER: The allegations contained in Paragraph 149 of Plaintiff's Complaint are not directed towards the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 149 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 149 of Plaintiff's Complaint.

150. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

ANSWER: The allegations contained in Paragraph 150 of Plaintiff's Complaint are not directed towards the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 150 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 150 of Plaintiff's Complaint.

151. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ANSWER: The allegations contained in Paragraph 151 of Plaintiff's Complaint are not directed towards the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 151 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 151 of Plaintiff's Complaint.

Regarding "ii. PPI-Induced Acute Kidney Injury ("AKI")"

152. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

ANSWER: The allegations contained in Paragraph 152 of Plaintiff's Complaint are not directed towards the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 152 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 152 of Plaintiff's Complaint.

153. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

ANSWER: The allegations contained in Paragraph 153 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 153 and state that the studies speak for themselves.

154. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

ANSWER: The allegations contained in Paragraph 154 of Plaintiff's Complaint are not directed to the GSK Defendants or Prevacid24HR and, accordingly, no response is required. To the extent a response is required, the GSK Defendants deny the allegations in Paragraph 154 and state that the studies speak for themselves.

155. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

ANSWER: The allegations contained in Paragraph 155 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants state that the Prevacid24HR label speaks for itself and, to the extent that the allegations purport to cast liability on the GSK Defendants, either directly or indirectly, those allegations are denied.

156. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

ANSWER: The allegations contained in Paragraph 156 of Plaintiff's Complaint are not directed to the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 156 calls for a medical conclusion, any such response by the

GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 156 of Plaintiff's Complaint.

Regarding "iii. PPI-Induced Chronic Kidney Disease ("CKD")"

157. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

ANSWER: The allegations contained in Paragraph 157 of Plaintiff's Complaint are not directed to the GSK Defendants or Prevacid24HR, and therefore, no response is required. Further, to the extent that Paragraph 157 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 157, as phrased.

158. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

ANSWER: The allegations contained in Paragraph 158 of Plaintiff's Complaint are not directed to the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 158 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 158, as phrased.

159. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

ANSWER: The allegations contained in Paragraph 159 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK

Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations and state that the publication speaks for itself.

160. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

ANSWER: The allegations contained in Paragraph 160 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations and state that the publication speaks for itself.

161. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

ANSWER: The allegations contained in Paragraph 161 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations and state that the publication speaks for itself.

162. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in

the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

ANSWER: The allegations contained in Paragraph 162 of Plaintiff's Complaint are not directed to the GSK Defendants or Prevacid24HR and, therefore, no response is required. Further, to the extent that Paragraph 162 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent a response is required, the GSK Defendants deny the allegations contained in Paragraph 162, as phrased.

163. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study "showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI." Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int'l 1482 (2017).

ANSWER: The allegations contained in Paragraph 163 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations and state that the publication speaks for itself.

164. To date, the labeling for Defendants' PPI Products lack adequate risk information about CKD.

ANSWER: The allegations contained in Paragraph 164 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants state that the Prevacid24HR label speaks for itself and, to

the extent that the allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

Regarding “C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency.”

165. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

ANSWER: The allegations contained in Paragraph 165 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Further, to the extent that Paragraph 165 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 165.

166. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

ANSWER: The allegations contained in Paragraph 166 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Further, to the extent that Paragraph 166 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 166.

167. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

ANSWER: The allegations contained in Paragraph 167 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that those allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

168. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases beyond their pre-PPI treatment levels.

ANSWER: The allegations contained in Paragraph 168 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Further, to the extent that Paragraph 168 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 168.

169. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

ANSWER: The allegations contained in Paragraph 169 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 169.

170. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and

will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

ANSWER: The allegations contained in Paragraph 170 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 170.

171. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

ANSWER: The allegations contained in Paragraph 171 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 171.

172. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

ANSWER: The allegations contained in Paragraph 172 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. Further, to the extent that Paragraph 172 calls for a medical conclusion, any such response by the GSK Defendants would be premature and inappropriate. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 172.

173. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

ANSWER: The allegations contained in Paragraph 173 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants state that the Prevacid24HR label speaks for itself and, to the extent that the allegations purport to cast liability upon the GSK Defendants, either directly or indirectly, those allegations are denied.

Regarding "D. Safer Alternatives to PPIs"

174. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as "H₂ Blockers") that were developed in the late 1960s. H₂ Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H₂ Blockers include Zantac, Pepcid and Tagamet. H₂ Blockers are not associated with an increased risk of kidney injuries.

ANSWER: The allegations contained in Paragraph 174 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 174.

175. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, Time to Halt the Overprescribing of Proton Pump Inhibitors, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

ANSWER: The allegations contained in Paragraph 175 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. However, to the extent that a response is required, the GSK Defendants deny these allegations and state that the publication speaks for itself.

176. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

ANSWER: The allegations contained in Paragraph 176 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 176.

Regarding "E. Injuries Resulting from PPI Products"

177. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear

and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

ANSWER: The allegations contained in Paragraph 177 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 177.

178. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

ANSWER: The allegations contained in Paragraph 178 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 178.

179. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

ANSWER: The allegations contained in Paragraph 179 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK

Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 179.

180. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

ANSWER: The allegations contained in Paragraph 180 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 180.

Regarding "F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products"

181. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

ANSWER: The allegations contained in Paragraph 181 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 181.

182. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and

Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

ANSWER: The allegations contained in Paragraph 182 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 182.

183. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

ANSWER: The allegations contained in Paragraph 183 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 183.

184. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form

Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

ANSWER: The allegations contained in Paragraph 184 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 184.

185. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

ANSWER: The allegations contained in Paragraph 185 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 185 and, therefore, deny the same.

186. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

ANSWER: The allegations contained in Paragraph 186 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 186.

187. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

ANSWER: The allegations contained in Paragraph 187 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 187.

188. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

ANSWER: The allegations contained in Paragraph 188 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 188.

189. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

ANSWER: The allegations contained in Paragraph 189 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 189.

190. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

ANSWER: The allegations contained in Paragraph 190 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 190.

191. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

ANSWER: The allegations contained in Paragraph 191 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 191.

192. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

ANSWER: The allegations contained in Paragraph 192 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 192.

193. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

ANSWER: The allegations contained in Paragraph 193 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 193.

194. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

ANSWER: The allegations contained in Paragraph 194 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations in Paragraph 194.

195. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

ANSWER: The allegations contained in Paragraph 195 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 195.

Regarding “G. Defendants Violations of Federal Law”

196. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 196 of Plaintiff’s Complaint.

197. With respect to Defendants’ PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Defendants’ PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;

b. Defendants’ PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. Defendants’ PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

d. Defendants’ PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;

n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up";

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant's PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ANSWER: The allegations contained in Paragraph 197 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 197.

REGARDING “ESTOPPEL FROM PLEADING AND TOLLING OF APPLICABLE STATUTES OF LIMITATIONS”

198. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: The GSK Defendants state that Paragraph 198 of Plaintiff’s Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 198.

199. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

ANSWER: The GSK Defendants state that Paragraph 199 of Plaintiff’s Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 199.

200. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

ANSWER: The allegations contained in Paragraph 200 of Plaintiff's Complaint constitute legal conclusions and, therefore, no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 200.

201. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

ANSWER: The allegations contained in Paragraph 201 of Plaintiff's Complaint constitute legal conclusions and, therefore, no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 201.

202. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

ANSWER: The allegations contained in Paragraph 202 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 202.

203. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

ANSWER: The allegations contained in Paragraph 203 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 203.

204. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 204 of Plaintiff's Complaint.

205. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

ANSWER: The GSK Defendants deny the allegations contained in Paragraph 205 of Plaintiff's Complaint.

206. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

ANSWER: The allegations contained in Paragraph 206 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations in Paragraph 206.

207. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

ANSWER: The allegations contained in Paragraph 207 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

208. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

ANSWER: The allegations contained in Paragraph 208 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

209. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

ANSWER: The allegations contained in Paragraph 209 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

210. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

ANSWER: The allegations contained in Paragraph 210 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 210.

211. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

ANSWER: The allegations contained in Paragraph 211 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

REGARDING "CAUSES OF ACTION"
REGARDING "COUNT I STRICT PRODUCT LIABILITY"

212. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 212 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 212.

213. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

ANSWER: The allegations contained in Paragraph 213 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 213.

214. At the time of the Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

ANSWER: The allegations contained in Paragraph 214 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 214.

215. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

ANSWER: The allegations contained in Paragraph 215 of Plaintiff's Complaint are directed at products other than Prevacid24HR and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR, the GSK Defendants deny the allegations contained in Paragraph 215.

216. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

ANSWER: The allegations contained in Paragraph 216 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 216.

217. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including the Plaintiff.

ANSWER: The allegations contained in Paragraph 217 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 217.

218. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

ANSWER: The allegations contained in Paragraph 218 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 218.

219. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

ANSWER: The allegations contained in Paragraph 219 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 219.

220. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: The allegations contained in Paragraph 220 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 220.

221. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

ANSWER: The allegations contained in Paragraph 221 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 221.

222. At the time, the Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: The allegations contained in Paragraph 222 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

223. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

ANSWER: The allegations contained in Paragraph 223 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 223.

224. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

ANSWER: The allegations contained in Paragraph 224 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 224 as phrased.

225. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

ANSWER: The allegations contained in Paragraph 225 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 225.

226. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

ANSWER: The allegations contained in Paragraph 226 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 226.

227. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

ANSWER: The allegations contained in Paragraph 227 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 227.

228. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

ANSWER: The allegations contained in Paragraph 228 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 228.

229. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

ANSWER: The allegations contained in Paragraph 229 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 229.

230. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

ANSWER: The allegations contained in Paragraph 230 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 230.

231. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

ANSWER: The allegations contained in Paragraph 231 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 231.

232. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

ANSWER: The allegations contained in Paragraph 232 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 232.

233. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

ANSWER: The allegations contained in Paragraph 233 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 233.

234. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate

postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

ANSWER: The allegations contained in Paragraph 234 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 234.

235. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

ANSWER: The allegations contained in Paragraph 235 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

236. Plaintiff did not misuse or materially alter the PPI Products.

ANSWER: The allegations contained in Paragraph 236 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient

knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

237. Defendants are strictly liable for the Plaintiff's injuries in the following ways:

a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;

c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;

d. Defendants failed to adequately test their PPI Products;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and

f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

ANSWER: The allegations contained in Paragraph 237 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 237.

238. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

ANSWER: The allegations contained in Paragraph 238 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 238.

239. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: The allegations contained in Paragraph 239 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 239.

240. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

ANSWER: The allegations contained in Paragraph 240 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 240.

241. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 241 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 241.

242. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, the Plaintiff, and/or the Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 242 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 242.

WHEREFORE, the Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING “COUNT II STRICT PRODUCT LIABILITY-DESIGN DEFECT”

243. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. The Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: The GSK Defendants state that Paragraph 243 of Plaintiff’s Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 243.

244. At all times relevant, Defendants’ PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

ANSWER: The allegations contained in Paragraph 244 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 244.

245. Defendants’ PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

ANSWER: The allegations contained in Paragraph 245 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 245.

246. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

ANSWER: The allegations contained in Paragraph 246 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 246.

247. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

ANSWER: The allegations contained in Paragraph 247 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

248. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

ANSWER: The allegations contained in Paragraph 248 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 248.

249. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

ANSWER: The allegations contained in Paragraph 249 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of these allegations and, therefore, deny the same.

250. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

ANSWER: The allegations contained in Paragraph 250 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 250.

251. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

ANSWER: The allegations contained in Paragraph 251 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 251.

252. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

ANSWER: The allegations contained in Paragraph 252 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 252.

253. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

ANSWER: The allegations contained in Paragraph 253 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 253.

254. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

ANSWER: The allegations contained in Paragraph 254 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 254.

255. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiff specifically were not aware of these risks, nor would they expect such risks.

ANSWER: The allegations contained in Paragraph 255 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegation that it is unlikely that users would be aware of the risks associated with Prevacid24HR. The GSK Defendants state that they lack sufficient knowledge or information to form a belief regarding the truth of the remaining allegations contained in Paragraph 255 and, therefore, deny the same.

256. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with the design or formulation of the PPI Products, as defined by Ohio Rev. Code. §§ 2307.75(C), or they were more dangerous than an ordinary consumer would expect.

ANSWER: The allegations contained in Paragraph 256 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 256.

257. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, as defined at Ohio Rev. Code. §§ 2307.75(B)(1)-(5), include but are not limited to the following:

a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);

b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);

c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);

d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions,

while not as prone to cause injury, as defined at Ohio Rev. Code §§ 2307.75(B)(4), specifically, the risk of kidney injuries.

e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

ANSWER: The allegations contained in Paragraph 257 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 257.

258. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

ANSWER: The allegations contained in Paragraph 258 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 258.

259. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

ANSWER: The allegations contained in Paragraph 259 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegation that Prevacid24HR's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. The GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 259 and, therefore, deny the same.

260. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: The allegations contained in Paragraph 260 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 260.

261. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

ANSWER: The allegations contained in Paragraph 261 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 261.

262. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

ANSWER: The allegations contained in Paragraph 262 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 262.

263. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 263 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 263.

264. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

ANSWER: The allegations contained in Paragraph 264 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 264.

265. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

ANSWER: The allegations contained in Paragraph 265 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 265.

266. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

ANSWER: The allegations contained in Paragraph 266 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 266.

267. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

ANSWER: The allegations contained in Paragraph 267 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 267.

268. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

ANSWER: The allegations contained in Paragraph 268 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 268.

269. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

ANSWER: The allegations contained in Paragraph 269 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief regarding the truth of the allegations that Plaintiffs

were specifically unaware of any alleged risk of kidney injuries. The GSK Defendants deny the remaining allegations contained in Paragraph 269.

270. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

ANSWER: The allegations contained in Paragraph 270 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 270.

271. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: The allegations contained in Paragraph 271 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 271.

272. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: The allegations contained in Paragraph 272 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 272.

273. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

ANSWER: The allegations contained in Paragraph 273 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 273.

274. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff's injuries and damages.

ANSWER: The allegations contained in Paragraph 274 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 274.

275. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

ANSWER: The allegations contained in Paragraph 275 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 275.

276. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: The allegations contained in Paragraph 276 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 276.

277. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

ANSWER: The allegations contained in Paragraph 277 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 277.

278. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: The allegations contained in Paragraph 278 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 278.

279. The defective nature of the PPI Products was a substantial factor in causing Plaintiff's injuries.

ANSWER: The allegations contained in Paragraph 279 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 279.

280. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 280 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 280.

281. Defendants' conduct, as described herein, was extreme and outrageous.

ANSWER: The allegations contained in Paragraph 281 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 281.

282. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 282 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 282.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING “COUNT III STRICT PRODUCT LIABILITY – FAILURE TO WARN”

283. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: The GSK Defendants state that Paragraph 283 of Plaintiff’s Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 283.

284. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants’ knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

ANSWER: The allegations contained in Paragraph 284 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 284.

285. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare

providers of the product, knowing the product could cause serious injury, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

ANSWER: The allegations contained in Paragraph 285 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 285.

286. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

ANSWER: The allegations contained in Paragraph 286 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 286.

287. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

ANSWER: The allegations contained in Paragraph 287 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 287.

288. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

ANSWER: The allegations contained in Paragraph 288 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 288.

289. The risks of PPI Products were not open and obvious, as defined at Ohio Rev. Code Code §§ 2307.76(B).

ANSWER: The allegations contained in Paragraph 289 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 289.

290. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

ANSWER: The allegations contained in Paragraph 290 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 290.

291. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: The allegations contained in Paragraph 291 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 291.

292. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: The allegations contained in Paragraph 292 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 292.

293. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

ANSWER: The allegations contained in Paragraph 293 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 293.

294. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

ANSWER: The allegations contained in Paragraph 294 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief regarding the truth of the allegations contained in Paragraph 294 and, therefore, deny the same.

295. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

ANSWER: The allegations contained in Paragraph 295 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 295.

296. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

ANSWER: The allegations contained in Paragraph 296 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 296 as phrased.

297. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

ANSWER: The allegations contained in Paragraph 297 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 297.

298. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

ANSWER: The allegations contained in Paragraph 298 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations that they failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the alleged risks associated with Prevacid24HR and that they subjected Plaintiff to risks that exceeded the benefits of Prevacid24HR to the Plaintiffs. The GSK Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 298.

299. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

ANSWER: The allegations contained in Paragraph 299 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 299.

300. Had Plaintiff and/or her healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

ANSWER: The allegations contained in Paragraph 300 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 300.

301. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

ANSWER: The allegations contained in Paragraph 301 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 301.

302. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: The allegations contained in Paragraph 302 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 302.

303. Plaintiff and her healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: The allegations contained in Paragraph 303 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 303.

304. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

ANSWER: The allegations contained in Paragraph 304 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 304.

305. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

ANSWER: The allegations contained in Paragraph 305 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 305.

306. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

ANSWER: The allegations contained in Paragraph 306 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants state that they lack sufficient knowledge or information to form a belief regarding the truth of the allegations contained in Paragraph 306 and, therefore, deny the same.

307. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

ANSWER: The allegations contained in Paragraph 307 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 307.

308. Defendants' conduct as described herein was a substantial factor in causing Plaintiff's injuries.

ANSWER: The allegations contained in Paragraph 308 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 308.

309. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: The allegations contained in Paragraph 309 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 309.

310. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 310 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 310.

311. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

ANSWER: The allegations contained in Paragraph 311 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 311.

312. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 312 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 312.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT IV NEGLIGENCE"

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 313 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 313.

314. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

ANSWER: The allegations contained in Paragraph 314 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 314.

315. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

ANSWER: The allegations contained in Paragraph 315 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 315.

316. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence

and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;

h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;

i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;

j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;

k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;

l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;

m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;

n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;

o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;

p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;

q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;

r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;

s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;

t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;

u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associated with use of their PPI Products;

v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;

w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;

x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;

y. Failing to use due care under the circumstances; and

z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

ANSWER: The allegations contained in Paragraph 316 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 316.

317. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

ANSWER: The allegations contained in Paragraph 317 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 317.

318. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

ANSWER: The allegations contained in Paragraph 318 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 318.

319. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

ANSWER: The allegations contained in Paragraph 319 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 319.

320. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

ANSWER: The allegations contained in Paragraph 320 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 320.

321. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ANSWER: The allegations contained in Paragraph 321 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 321.

322. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

ANSWER: The allegations contained in Paragraph 322 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 322.

323. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: The allegations contained in Paragraph 323 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 323.

324. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

ANSWER: The allegations contained in Paragraph 324 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 324.

325. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 325 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 325.

326. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 326 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 326.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT V NEGLIGENCE PER SE"

327. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 327 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 327.

328. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

ANSWER: The allegations contained in Paragraph 328 of Plaintiff's Complaint are directed at parties and entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 328.

329. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

ANSWER: The allegations contained in Paragraph 329 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

330. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

ANSWER: The allegations contained in Paragraph 330 of Plaintiff's Complaint are directed at parties and entities other than the GSK Defendants and constitute legal conclusions and,

accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 330.

331. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

ANSWER: The allegations contained in Paragraph 331 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

332. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

ANSWER: The allegations contained in Paragraph 332 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

333. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 333 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

334. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 334 of Plaintiff's Complaint are directed at parties and entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 334.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT VI NEGLIGENCE—FAILURE TO TEST"

335. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 335 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 335.

336. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

ANSWER: The allegations contained in Paragraph 336 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 336.

337. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

ANSWER: The allegations contained in Paragraph 337 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 337.

338. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

ANSWER: The allegations contained in Paragraph 338 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 338.

339. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

ANSWER: The allegations contained in Paragraph 339 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 339.

340. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

ANSWER: The allegations contained in Paragraph 340 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 340.

341. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

ANSWER: The allegations contained in Paragraph 341 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 341.

342. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure caused by the use of the PPI Products.

ANSWER: The allegations contained in Paragraph 342 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 342.

343. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

ANSWER: The allegations contained in Paragraph 343 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 343.

344. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

ANSWER: The allegations contained in Paragraph 344 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed

to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 344.

345. Defendants are strictly liable for the Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

ANSWER: The allegations contained in Paragraph 345 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 345.

346. As a direct and proximate result of Defendants' wrongful actions and failure to test, the Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

ANSWER: The allegations contained in Paragraph 346 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 346.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**REGARDING “COUNT VII STRICT PRODUCTS LIABILITY DUE TO NON
CONFORMANCE WITH REPRESENTATIONS PURSUANT TO R.C. 2307.77”**

347. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: The GSK Defendants state that Paragraph 347 of Plaintiff’s Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 347.

348. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of PPI Products and made representations regarding the character or quality of PPI Products including but not limited to the fact that PPI Products were safe and effective in its ordinary use.

ANSWER: The allegations contained in Paragraph 348 of Plaintiff’s Complaint are directed to parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants admit that they currently market Prevacid24HR. The GSK Defendants lack sufficient knowledge or information to formulate a belief regarding the truth of the remaining allegations in Paragraph 348 and, therefore, deny the same.

349. The PPI Products manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

ANSWER: The allegations contained in Paragraph 349 of Plaintiff’s Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 349.

350. These material misrepresentations made by the Defendants were false.

ANSWER: The allegations contained in Paragraph 350 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 350.

351. Plaintiff justifiably relied upon Defendants' representations regarding PPI Products.

ANSWER: The allegations contained in Paragraph 351 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 351.

352. Upon information and belief, the warnings provided to those who chose to use the PPI Products, including the Plaintiff were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

ANSWER: The allegations contained in Paragraph 352 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 352.

353. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

ANSWER: The allegations contained in Paragraph 353 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 353.

354. As a direct and proximate result of the foregoing, Plaintiff are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

ANSWER: The allegations contained in Paragraph 354 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 354.

355. Further, as a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries; and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

ANSWER: The allegations contained in Paragraph 355 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 355.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT VIII BREACH OF EXPRESS WARRANTY"

356. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 356 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 356.

357. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

ANSWER: The allegations contained in Paragraph 357 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 357.

358. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

ANSWER: The allegations contained in Paragraph 358 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 358.

359. Defendants expressly warranted that their PPI Products were safe and effective to use.

ANSWER: The allegations contained in Paragraph 359 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 359.

360. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

ANSWER: The allegations contained in Paragraph 360 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 360.

361. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

ANSWER: The allegations contained in Paragraph 361 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 361.

362. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

ANSWER: The allegations contained in Paragraph 362 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 362.

363. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

ANSWER: The allegations contained in Paragraph 363 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 363.

364. Defendants breached their express warranty in one or more of the following ways:

a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;

c. Defendants failed to adequately test their PPI Products; and,

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

ANSWER: The allegations contained in Paragraph 364 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 364.

365. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

ANSWER: The allegations contained in Paragraph 365 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 365.

366. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

ANSWER: The allegations contained in Paragraph 366 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 366.

367. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

ANSWER: The allegations contained in Paragraph 367 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 367.

368. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

ANSWER: The allegations contained in Paragraph 368 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 368.

369. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

ANSWER: The allegations contained in Paragraph 369 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 369.

370. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

ANSWER: The allegations contained in Paragraph 370 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 370.

371. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

ANSWER: The allegations contained in Paragraph 371 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 371.

372. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

ANSWER: The allegations contained in Paragraph 372 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 372.

373. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

ANSWER: The allegations contained in Paragraph 373 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 373.

374. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 374 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 374.

375. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with

knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 375 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 375.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT IX BREACH OF IMPLIED WARRANTY"

376. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 376 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 376.

377. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

ANSWER: The allegations contained in Paragraph 377 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 377.

378. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

ANSWER: The allegations contained in Paragraph 378 of Plaintiff's Complaint constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 378.

379. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

ANSWER: The allegations contained in Paragraph 379 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 379.

380. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: The allegations contained in Paragraph 380 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 380.

381. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

ANSWER: The allegations contained in Paragraph 381 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 381.

382. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

ANSWER: The allegations contained in Paragraph 382 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 382.

383. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: The allegations contained in Paragraph 383 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 383.

384. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: The allegations contained in Paragraph 384 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 384.

385. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

ANSWER: The allegations contained in Paragraph 385 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 385.

386. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

ANSWER: The allegations contained in Paragraph 386 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 386.

387. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

ANSWER: The allegations contained in Paragraph 387 of Plaintiff's Complaint are directed at parties or entities other than GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 387.

388. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 388 of Plaintiff's Complaint are directed at parties or entities other than GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 388.

389. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 389 of Plaintiff's Complaint are directed at parties or entities other than GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 389.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT X NEGLIGENT MISREPRESENTATION"

390. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the

broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 390 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 390.

391. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

ANSWER: The allegations contained in Paragraph 391 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 391.

392. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

ANSWER: The allegations contained in Paragraph 392 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 392.

393. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and her healthcare providers, as to the health risks and consequences of the use of their PPI Products.

ANSWER: The allegations contained in Paragraph 393 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 393.

394. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: The allegations contained in Paragraph 394 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 394.

395. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demands for, as well as the ultimate prescription, purchase and use of their PPI Products.

ANSWER: The allegations contained in Paragraph 395 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 395.

396. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

ANSWER: The allegations contained in Paragraph 396 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 396.

397. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

ANSWER: The allegations contained in Paragraph 397 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 397.

398. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

ANSWER: The allegations contained in Paragraph 398 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 398.

399. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 399 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 399.

400. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 400 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 400.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT XI FRAUD AND FRAUDULENT MISREPRESENTATION"

401. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the

broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 401 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 401.

402. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

ANSWER: The allegations contained in Paragraph 402 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 402.

403. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

ANSWER: The allegations contained in Paragraph 403 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 403.

404. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

ANSWER: The allegations contained in Paragraph 404 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 404.

405. These representations made by Defendants were false and misleading.

ANSWER: The allegations contained in Paragraph 405 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 405.

406. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

ANSWER: The allegations contained in Paragraph 406 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the

allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 406.

407. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

ANSWER: The allegations contained in Paragraph 407 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 407.

408. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

ANSWER: The allegations contained in Paragraph 408 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 408.

409. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

ANSWER: The allegations contained in Paragraph 409 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to

Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 409.

410. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

ANSWER: The allegations contained in Paragraph 410 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 410.

411. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: The allegations contained in Paragraph 411 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 411.

412. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 412 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 412.

413. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 413 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 413.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT XII GROSS NEGLIGENCE"

414. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 414 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 414.

415. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

ANSWER: The allegations contained in Paragraph 415 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 415.

416. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which

proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

ANSWER: The allegations contained in Paragraph 416 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 416.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "COUNT XIII FRAUDULENT CONCEALMENT"

417. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 417 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 417.

418. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including

information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

ANSWER: The allegations contained in Paragraph 418 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 418.

419. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

ANSWER: The allegations contained in Paragraph 419 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 419.

420. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

ANSWER: The allegations contained in Paragraph 420 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 420.

421. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

ANSWER: The allegations contained in Paragraph 421 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 421.

422. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

ANSWER: The allegations contained in Paragraph 422 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 422.

423. Plaintiff and/or her healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have

been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

ANSWER: The allegations contained in Paragraph 423 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 423.

424. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: The allegations contained in Paragraph 424 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 424.

425. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

ANSWER: The allegations contained in Paragraph 425 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

426. Defendants also had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

ANSWER: The allegations contained in Paragraph 426 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that they purport to cast liability, either directly or indirectly, upon the GSK Defendants, those allegations are denied.

427. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

ANSWER: The allegations contained in Paragraph 427 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 427.

428. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

ANSWER: The allegations contained in Paragraph 428 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 428.

429. Plaintiff's healthcare providers were not provided the necessary information by The Defendants to provide an adequate warning to the Plaintiff.

ANSWER: The allegations contained in Paragraph 429 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 429.

430. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

ANSWER: The allegations contained in Paragraph 430 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 430.

431. The PPI Products were improperly marketed to the Plaintiff and/or her healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

ANSWER: The allegations contained in Paragraph 431 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 431.

432. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

ANSWER: The allegations contained in Paragraph 432 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 432.

433. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and the Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

ANSWER: The allegations contained in Paragraph 433 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 433.

434. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

ANSWER: The allegations contained in Paragraph 434 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no

response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 434.

435. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

ANSWER: The allegations contained in Paragraph 435 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 435.

436. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

ANSWER: The allegations contained in Paragraph 436 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 436.

437. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare

providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

ANSWER: The allegations contained in Paragraph 437 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 437.

438. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

ANSWER: The allegations contained in Paragraph 438 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 438.

439. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

ANSWER: The allegations contained in Paragraph 439 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 439.

440. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

ANSWER: The allegations contained in Paragraph 440 of Plaintiff's Complaint are directed at parties or entities other than the GSK Defendants and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 440.

441. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous.

Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 441 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 441.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**REGARDING "COUNT XIV VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES"**

442. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: The GSK Defendants state that Paragraph 442 of Plaintiff's Complaint contains statements to which no response is required. To the extent that a response is required, the GSK Defendants deny the allegations contained in Paragraph 442.

443. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

ANSWER: The allegations contained in Paragraph 443 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 443.

444. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, Ohio Rev. Code Ann. §§ 1345.01.

ANSWER: The allegations contained in Paragraph 444 of Plaintiff's Complaint are directed at parties or entities other the GSK Defendants and constitute legal conclusions and, accordingly,

no response is required from the GSK Defendants. To the extent that the allegations are directed to the GSK Defendants and a response is required, the GSK Defendants deny the allegations contained in Paragraph 444.

445. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: The allegations contained in Paragraph 445 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 445.

446. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: The allegations contained in Paragraph 446 of Plaintiff's Complaint are directed at products other than Prevacid24HR and constitute legal conclusions and, accordingly, no response is required from the GSK Defendants. To the extent that the allegations are directed to Prevacid24HR and a response is required, the GSK Defendants deny the allegations contained in Paragraph 446.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

REGARDING "PRAYER FOR RELIEF"

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

ANSWER: Furthermore, responding to the unnumbered Paragraph following Paragraph 446 of Plaintiff's Complaint beginning "WHEREFORE," the GSK Defendants deny the allegations

contained in such Paragraph. The GSK Defendants further deny each and every allegation not specifically admitted herein. The GSK Defendants deny that Plaintiffs are entitled to any relief requested in Plaintiff's Complaint.

GSK DEFENDANTS' AFFIRMATIVE DEFENSES

FIRST DEFENSE

Plaintiff's Complaint fails to state a claim or claims upon which relief can be granted.

SECOND DEFENSE

Plaintiff's Complaint fails to state claim or claims upon which relief can be granted due to lack of adequate product identification.

THIRD DEFENSE

The Plaintiff may be barred from bringing some of the claims alleged in the Complaint because the Plaintiff may lack standing and/or capacity to bring such claims.

FOURTH DEFENSE

The sole proximate cause of the Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions the GSK Defendants were and are in no way liable.

FIFTH DEFENSE

If the Plaintiff has been damaged, which the GSK Defendants deny, any recovery by the Plaintiff is barred to the extent they voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiff has failed to mitigate alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

SIXTH DEFENSE

The Plaintiff failed to exercise ordinary care for their own safety such that the Plaintiff is not entitled to recover.

SEVENTH DEFENSE

The injuries and damages allegedly sustained by the Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in the Plaintiff over which the GSK Defendants had no control.

EIGHTH DEFENSE

The Plaintiff's causes of action may be barred by the applicable statute of limitations and/or statute of repose.

NINTH DEFENSE

The Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver, estoppel and/or regulatory compliance.

TENTH DEFENSE

There was no defect in the products at issue with the result that the Plaintiff is not entitled to recover against the GSK Defendants in this cause.

ELEVENTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover against the GSK Defendants in this cause.

TWELFTH DEFENSE

If Plaintiff has been damaged, which the GSK Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

THIRTEENTH DEFENSE

If Plaintiff has been damaged, which the GSK Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct the GSK Defendants are not legally responsible.

FOURTEENTH DEFENSE

If Plaintiff suffered any damages or injuries, which are denied, the Plaintiff's recovery is barred, in whole or in part, or subject to reduction under the doctrine of contributory and/or comparative negligence.

FIFTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that the Plaintiff is entitled to recover against the GSK Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiff, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the Plaintiffs have settled or may settle in the future.

SIXTEENTH DEFENSE

If the Plaintiff has been damaged, which the GSK Defendants deny, the negligence or fault of the Plaintiff constitutes the sole, intervening, and superseding cause of the Plaintiff's alleged damages.

SEVENTEENTH DEFENSE

If the Plaintiff has been damaged, which the GSK Defendants deny, the negligence or fault of persons and/or entities for whose conduct the GSK Defendants are not legally

responsible constitutes the sole, intervening, and superseding cause of the Plaintiff's alleged damages.

EIGHTEENTH DEFENSE

If the Plaintiff has been damaged, which the GSK Defendants deny, the actions of persons or entities for whose conduct the GSK Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of the Plaintiff's alleged damages.

NINETEENTH DEFENSE

If Plaintiff has been damaged, which the GSK Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which the GSK Defendants are not legally responsible.

TWENTIETH DEFENSE

If Plaintiff has been damaged, which the GSK Defendants deny, such damages were caused by abuse, misuse, user error and/or modification of the products at issue for which the GSK Defendants were and are in no way liable.

TWENTY-FIRST DEFENSE

The GSK Defendants made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the Plaintiff. To the extent applicable, the Plaintiff's breach of warranty claims are barred by a lack of privity between the Plaintiff and the GSK Defendants. To the extent the Plaintiff makes warranty claims, whether

express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the Plaintiff's lack of reliance on any such warranties, and by waiver.

TWENTY-SECOND DEFENSE

To the extent the Plaintiff asserts a claim for breach of implied warranty, such claim must fail because the products were not used for their ordinary purpose.

TWENTY-THIRD DEFENSE

To the extent the Plaintiff asserts a claim for breach of warranty, such claim is barred because the Plaintiff did not first give notice of any alleged defect of the products to the GSK Defendants.

TWENTY-FOURTH DEFENSE

The GSK Defendants neither had nor breached any alleged duty to warn with respect to the products, with the result that the Plaintiff is not entitled to recover in this cause.

TWENTY-FIFTH DEFENSE

Plaintiff's claims are barred by the learned intermediary doctrine.

TWENTY-SIXTH DEFENSE

The conduct of the GSK Defendants and the subject products at all times conformed to the Federal Food, Drug and Cosmetic Act, and other pertinent federal statute and regulations. Accordingly, the Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

TWENTY-SEVENTH DEFENSE

The Plaintiff's alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of the GSK Defendants.

TWENTY-EIGHTH DEFENSE

If the Plaintiff recovers from the GSK Defendants, it is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiff's alleged damages.

TWENTY-NINTH DEFENSE

Plaintiff's claims are or may be barred, in whole or in part, to the extent that the Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. The GSK Defendants are entitled to a set-off for the entire amount of proceeds the Plaintiff has or may recover from all other sources.

THIRTIETH DEFENSE

Should the GSK Defendants be held liable to the Plaintiff, which liability is specifically denied, the GSK Defendants would be entitled to a set-off for the total of all amounts paid to the Plaintiff from all collateral sources.

THIRTY-FIRST DEFENSE

The GSK Defendants assert any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserves the right to amend its Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-SECOND DEFENSE

The product at issue is neither defective nor unreasonably dangerous because it is a product falling within what is commonly known as Comments (j) and (k), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the product at issue was, at all times material to the Master Complaint, reasonably safe and reasonably fit for their intended use, and the warnings and instructions accompanying the products at the time of the occurrence or injuries alleged by the Plaintiff was legally adequate.

THIRTY-THIRD DEFENSE

The Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the products were manufactured and marketed.

THIRTY-FOURTH DEFENSE

The Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed to industry custom/usage standards and/or legislative/administrative/regulatory standards.

THIRTY-FIFTH DEFENSE

The design complained of in Plaintiff's Complaint, the alleged defects of the products, and/or any alternative design claimed by the Plaintiff were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-SIXTH DEFENSE

The GSK Defendants specifically plead all affirmative defenses under the Uniform Commercial Code (“UCC”) now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

THIRTY-SEVENTH DEFENSE

No act or omission of the GSK Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

THIRTY-EIGHTH DEFENSE

To the extent the Plaintiff asserts a demand for punitive damages, the GSK Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513(2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

THIRTY-NINTH DEFENSE

To the extent that the Plaintiff asserts a claim for punitive damages, that claim is in contravention of the rights of the GSK Defendants under the following constitutional provisions:

1. Plaintiff’s claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the applicable State Constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiff satisfying a burden of proof which is less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate

the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(h) the award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law; and (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the FDA-approved product labeling, the prescribing physicians, or other persons or entities.

FORTY-FIRST DEFENSE

There should be no recovery against the GSK Defendants for any failure to warn or inadequacy of warning, because at all pertinent times, Plaintiff possessed or should have possessed good and adequate knowledge which negated any need for warning.

FORTY-SECOND DEFENSE

If Plaintiff was injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product manufactured by the GSK Defendants.

FORTY-THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, because the GSK Defendants at all relevant times, complied with all applicable laws and regulations.

FORTY-FOURTH DEFENSE

Plaintiff's product-liability claims are barred because the benefits of the products outweighed their risks.

FORTY-FIFTH DEFENSE

Venue may be improper in any individual case where the Plaintiff does not reside in the forum wherein his or her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

FORTY-SIXTH DEFENSE

Plaintiff's case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

FORTY-SEVENTH DEFENSE

The GSK Defendants are entitled to and claim the benefits of all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

FORTY-EIGHTH DEFENSE

Plaintiff has failed to plead their fraud claims with the particularity required under the applicable state's statutory and/or common law.

FORTY-NINTH DEFENSE

If it should be proven that any product distributed by the GSK Defendants was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that the GSK Defendants neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

FIFTIETH DEFENSE

The damages claimed by Plaintiff are not recoverable, in whole or in part, under the various applicable states' laws.

FIFTY-FIRST DEFENSE

Plaintiff's claims may be barred by failure to join indispensable parties.

FIFTY-SECOND DEFENSE

The GSK Defendants hereby give notice that they intend to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

FIFTY-THIRD DEFENSE

Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and the GSK Defendants hereby assert all allowable limitations and defenses under the Ohio Products Liability Act.

FIFTY-FOURTH DEFENSE

The GSK Defendants hereby plead all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22–2307.29.

FIFTY-FIFTH DEFENSE

Plaintiff's claims are barred because Prevacid®24HR is an “ethical drug” as defined by Ohio Rev. Code Ann. § 2037.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.

FIFTY-SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in Ohio Rev. Code Ann. §§ 2315.22, *et seq.* and 2315.32–2315.36.

FIFTY-SEVENTH DEFENSE

Plaintiff's recovery against the GSK Defendants should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.

FIFTY-EIGHTH DEFENSE

Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including, but not limited to, those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.

FIFTY-NINTH DEFENSE

Plaintiff's claims for punitive or exemplary damages as set forth in the Complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).

SIXTIETH DEFENSE

Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

SIXTY-FIRST DEFENSE

Ohio's Consumer Sales Practices Act, Ohio Rev. C. §1345.12(C), specifically precludes claims for personal injury or death.

SIXTY-SECOND DEFENSE

Plaintiff fails to state a claim for relief under Ohio Rev. Code Ann. §§ 1345.01, *et seq.*

SIXTY-THIRD DEFENSE

Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.*, is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

SIXTY-FOURTH DEFENSE

Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.*, unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

SIXTY-FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code § 2307.711.

SIXTY-SIXTH DEFENSE

All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct the GSK Defendants had no reason to anticipate and for whose conduct the GSK Defendants are not and were not responsible. Ohio Revised Code § 2307.22, *et seq.*

SIXTY-SEVENTH DEFENSE

The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code Ann. § 2307.23.

SIXTY-EIGHTH DEFENSE

One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Revised Code §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, *et al.*

SIXTY-NINTH DEFENSE

Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(D) because adequate warning and instruction were provided under Ohio Revised Code § 2307.76 concerning any unavoidably unsafe aspects of the product.

SEVENTIETH DEFENSE

Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

SEVENTY-FIRST DEFENSE

Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Revised Code § 2307.75(F).

SEVENTY-SECOND DEFENSE

Plaintiff's inadequate warning claims are barred under Ohio Revised Code § 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

SEVENTY-THIRD DEFENSE

The GSK Defendants intend to rely upon any additional affirmative defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

WHEREFORE, the GSK Defendants deny that they are liable to Plaintiff and demand judgment in their favor against Plaintiff, dismissing the Complaint with prejudice, and awarding their costs and such other and further relief as may be just and proper.

Respectfully submitted,

/s/ Frank C. Woodside, III

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JURY DEMAND

Pursuant to Ohio Civil Rule 38, the GSK Defendants request a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Frank C. Woodside, III

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July, 2019, a copy of the foregoing was electronically filed with the Clerk of Courts for the Hamilton County Court of Common Pleas. A copy of the foregoing was also served on the below-listed parties this same date by First Class, United States Mail, postage prepaid.

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**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A. BEHYMER : **No. A1902638**
Plaintiff : **DEFENDANT PFIZER INC.'S**
vs. : **ANSWER TO PLAINTIFF'S**
: **COMPLAINT**
ABBOTT LABORATORIES, et al. : **JURY DEMAND ENDORSED**
Defendants : **HEREON**
: **Judge Charles J. Kubicki, Jr.**

Defendant Pfizer Inc. ("Pfizer") states and avers the following as its Answer to the Complaint of Plaintiff Teresa A. Behymer ("Plaintiff"):

FIRST DEFENSE

1. The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

2. Pfizer denies the averments contained in paragraph 1 of the Complaint.
3. The averments contained in paragraph 2 of the Complaint do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.
4. Pfizer denies the averments contained in paragraphs 3-4 of the Complaint.
5. Pfizer admits that Protonix and Nexium 24HR are proton pump inhibitors and are indicated for the FDA-approved uses and doses. Pfizer denies any remaining averments contained in paragraph 5 of the Complaint.



VERIFY RECORD

6. The averments contained in paragraph 6 of the Complaint do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

7. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 7 of the Complaint regarding Plaintiff's use of the products noted or her alleged injury. Pfizer denies any remaining averments contained in said paragraph.

8. The averments contained in paragraphs 8-82 are not directed at Pfizer and so no response is required. To the extent a response is required, Pfizer lacks knowledge sufficient to form a belief as to the averments contained in said paragraphs.

9. Pfizer admits that Pfizer Inc. is a Delaware corporation with its principal place of business in New York. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining averments contained in paragraph 83 of the Complaint as to "all times relevant."

10. Pfizer admits that it has been involved in the research, manufacture, testing, advertisement, promotion, marketing, sale, and distribution of the medications Protonix and Nexium 24HR in the United States. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraph 84 of the Complaint as to "all relevant times." Pfizer denies the remaining averments contained in said paragraph.

11. Pfizer admits the averments contained in paragraphs 85-89 of the Complaint.

12. Pfizer denies the averments contained in paragraphs 90-91 of the Complaint.

13. The averments contained in paragraphs 92-123 are not directed at Pfizer and so no response is required. To the extent a response is required, Pfizer lacks knowledge sufficient to form a belief as to the averments contained in said paragraphs.

14. Pfizer admits it is a Fortune 500 Company but denies the remaining averments directed at it in paragraph 124 of the Complaint. Pfizer lacks knowledge sufficient to form a belief as to the remaining averments contained in said paragraph as to the other parties.

15. Pfizer denies the averments contained in paragraph 125 of the Complaint.

16. Pfizer admits that Protonix and Nexium 24HR are indicated for the FDA-approved uses and doses. Pfizer denies the remaining averments contained in paragraph 126 of the Complaint.

17. Pfizer refers to the FDA-approved labels for the mechanism of action for PPIs. Pfizer denies the remaining averments contained in paragraph 127 of the Complaint.

18. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraphs 128-130 of the Complaint.

19. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 131 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

20. To the extent Plaintiff is quoting from a document in paragraphs 132-142, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied. Pfizer denies the averments contained in said paragraphs.

21. In response to the averments contained in paragraph 143 of the Complaint, Pfizer admits that FDA considered and declined to include a warning about AIN in the Nexium 24HR label.

22. Pfizer denies the averments contained in paragraphs 144-145 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

23. Pfizer denies the averments contained in paragraphs 146-163 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

24. In response to the averments contained in paragraph 164 of the Complaint, Pfizer denies Plaintiff's characterization of the FDA-approved labeling for Protonix and Nexium 24HR and any risk of CKD. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

25. Pfizer denies the averments contained in paragraphs 165-166 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for

itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

26. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 167 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

27. Pfizer denies the averments contained in paragraphs 168-176 of the Complaint. To the extent Plaintiff is quoting from a document, that document speaks for itself, and any attempt to characterize it or selectively quote portions of it out of context is denied.

28. Pfizer denies the averments contained in paragraphs 177-197 of the Complaint.

29. In response to the averments contained in paragraph 198 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-197 of the Complaint.

30. The averments contained in paragraph 199 of the Complaint state a legal conclusion to which no response is required. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

31. Pfizer denies the averments contained in paragraphs 200-211 of the Complaint.

32. In response to the averments contained in paragraph 212 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-211 of the Complaint.

33. Pfizer denies the averments contained in paragraphs 213-215 of the Complaint.

34. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 216 of the Complaint.

35. Pfizer denies the averments contained in paragraphs 217-221 of the Complaint.

36. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 222 of the Complaint.

37. Pfizer denies the averments contained in paragraph 223 of the Complaint.

38. The averments contained in paragraph 224 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

39. Pfizer denies the averments contained in paragraphs 225-234 of the Complaint.

40. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraphs 235-236 of the Complaint.

41. Pfizer denies the averments contained in paragraphs 237-242 of the Complaint.

42. In response to the averments contained in paragraph 243 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-242 of the Complaint.

43. Pfizer denies the averments contained in paragraphs 244-246 of the Complaint.

44. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 247 of the Complaint.

45. Pfizer denies the averments contained in paragraph 248 of the Complaint.

46. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 249 of the Complaint.

47. Pfizer denies the averments contained in paragraphs 250-282 of the Complaint.

48. In response to the averments contained in paragraph 283 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-282 of the Complaint.

49. Pfizer denies the averments contained in paragraphs 284-293 of the Complaint.

50. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 294 of the Complaint.

51. Pfizer denies the averments contained in paragraphs 295-298 of the Complaint.

52. The averments contained in paragraph 299 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

53. Pfizer denies the averments contained in paragraphs 300-305 of the Complaint.

54. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 306 of the Complaint.

55. Pfizer denies the averments contained in paragraphs 307-312 of the Complaint.

56. In response to the averments contained in paragraph 313 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-312 of the Complaint.

57. The averments contained in paragraph 314 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

58. Pfizer denies the averments contained in paragraphs 315-326 of the Complaint.

59. In response to the averments contained in paragraph 327 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-326 of the Complaint.

60. Pfizer denies the averments contained in paragraph 328 of the Complaint.

61. The averments contained in paragraph 329 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

62. Pfizer denies the averments contained in paragraph 330 of the Complaint.

63. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraphs 331-332 of the Complaint.

64. Pfizer denies the averments contained in paragraphs 333-334 of the Complaint.

65. In response to the averments contained in paragraph 335 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-334 of the Complaint.

66. The averments contained in paragraph 336 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraph.

67. Pfizer denies the averments contained in paragraphs 337-346 of the Complaint.

68. In response to the averments contained in paragraph 347 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-346 of the Complaint.

69. In response to the averments contained in paragraph 348 of the Complaint, Pfizer admits that Protonix and Nexium 24HR are marketed consistent with the FDA-approved labels. Pfizer denies the remaining averments contained in said paragraph.

70. Pfizer denies the averments contained in paragraphs 349-350 of the Complaint.

71. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 351 of the Complaint.

72. Pfizer denies the averments contained in paragraphs 352-355 of the Complaint.

73. In response to the averments contained in paragraph 356 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-355 of the Complaint.

74. In response to the averments contained in paragraphs 357-360 of the Complaint, Pfizer admits that Protonix and Nexium 24HR are marketed consistent with the FDA-approved labels. Pfizer denies the remaining averments contained in said paragraphs.

75. Pfizer denies the averments contained in paragraph 361 of the Complaint.

76. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 362 of the Complaint.

77. Pfizer denies the averments contained in paragraphs 363-368 of the Complaint.

78. In response to the averments contained in paragraph 369 of the Complaint, Pfizer admits that Protonix and Nexium 24HR are marketed consistent with the FDA-approved labels. Pfizer denies the remaining averments contained in said paragraph.

79. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraphs 370-371 of the Complaint.

80. Pfizer denies the averments contained in paragraphs 372-375 of the Complaint.

81. In response to the averments contained in paragraph 376 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-375 of the Complaint.

82. In response to the averments contained in paragraph 377 of the Complaint, Pfizer admits that Protonix and Nexium 24HR are marketed consistent with the FDA-approved labels. Pfizer denies the remaining averments contained in said paragraph.

83. Pfizer denies the averments contained in paragraphs 378-379 of the Complaint.

84. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 380 of the Complaint.

85. Pfizer denies the averments contained in paragraphs 381-384 of the Complaint.

86. Pfizer lacks knowledge sufficient to form a belief as to the averments contained in paragraph 385 of the Complaint.

87. Pfizer denies the averments contained in paragraphs 386-389 of the Complaint.

88. In response to the averments contained in paragraph 390 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-389 of the Complaint.

89. Pfizer denies the averments contained in paragraphs 391-400 of the Complaint.

90. In response to the averments contained in paragraph 401 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-400 of the Complaint.

91. Pfizer denies the averments contained in paragraphs 402-413 of the Complaint.

92. In response to the averments contained in paragraph 414 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-413 of the Complaint.

93. Pfizer denies the averments contained in paragraphs 415-416 of the Complaint.

94. In response to the averments contained in paragraph 417 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-416 of the Complaint.

95. Pfizer denies the averments contained in paragraphs 418-424 of the Complaint.

96. The averments contained in paragraphs 425-426 of the Complaint state a legal conclusion and do not require a response. To the extent a response is required, Pfizer denies the averments contained in said paragraphs.

97. Pfizer denies the averments contained in paragraphs 427-441 of the Complaint.

98. In response to the averments contained in paragraph 442 of the Complaint, Pfizer incorporates by reference as if fully rewritten its responses to the averments contained in paragraphs 1-441 of the Complaint.

99. Pfizer denies the averments contained in paragraphs 443-446 of the Complaint.

THIRD DEFENSE

100. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

FOURTH DEFENSE

101. Plaintiff's claims are barred because the injuries allegedly sustained by Plaintiff were not proximately caused by any act or omission of Pfizer.

FIFTH DEFENSE

102. Plaintiff's recovery, if any, should be diminished, reduced, offset, or barred pursuant to the comparative and/or contributory negligence, fault, responsibility, or causation of others, including but not limited to Plaintiff.

SIXTH DEFENSE

103. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to assert them.

SEVENTH DEFENSE

104. Pfizer reserves the right to assert any and all available affirmative defenses under the laws of Ohio, or any State, Commonwealth, or District whose laws are or later become relevant in the course of this litigation.

EIGHTH DEFENSE

105. If Plaintiff was injured by Protonix and Nexium 24HR, those injuries occurred because the products were used for a purpose other than that for which they were intended, in a manner other than that in which they were intended to be used, and in disregard of instructions and directions regarding their use. Such misuse was not reasonably foreseeable to Pfizer.

NINTH DEFENSE

106. Plaintiff's alleged injuries and damages, if any, were caused in whole or in part by the acts and omissions, including, without limitation, misuse of Protonix and Nexium 24HR, of others over whom Pfizer had no authority or control and/or for whom Pfizer may not be held accountable.

TENTH DEFENSE

107. Plaintiff's claims are barred because any injuries and damages allegedly sustained by Plaintiff were the result of pre-existing or subsequent conditions that are unrelated to the use of Protonix and Nexium 24HR.

ELEVENTH DEFENSE

108. Plaintiff's claims are barred, in whole or in part, by reason of Plaintiff's failure to mitigate the alleged damages or losses.

TWELFTH DEFENSE

109. Plaintiff's claims are barred by the equitable doctrines of laches, waiver, estoppel, and/or statutory and regulatory compliance.

THIRTEENTH DEFENSE

110. Plaintiff's claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, and accord and satisfaction.

FOURTEENTH DEFENSE

111. Pfizer denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of Pfizer, or at the instruction or subject to the control of Pfizer with regard to any of the actions

described in the Complaint; thus, Pfizer is not liable for any acts or omissions of such third parties as a matter of law.

FIFTEENTH DEFENSE

112. Pfizer avers that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

SIXTEENTH DEFENSE

113. Plaintiff's claims are barred in whole or in part by comment k of section 402A of the Restatement (Second) of Torts and section 6(c) of the Restatement (Third) of Torts: Product Liability and their limitations upon the doctrine of strict product liability for purported design defect.

SEVENTEENTH DEFENSE

114. Plaintiff's claims are barred in whole or in part because Pfizer provided legally adequate "directions or warnings" as to the use of Protonix and Nexium 24HR within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

EIGHTEENTH DEFENSE

115. Pfizer provided adequate and complete warnings concerning Protonix and Nexium 24HR to Plaintiff's prescribing physicians. Therefore, any claim by Plaintiff for inadequate warnings is controlled by, and barred under, the learned intermediary doctrine.

NINETEENTH DEFENSE

116. Plaintiff's claims are barred, in whole or in part, by the lack of a defect, as Protonix and Nexium 24HR were properly prepared in accordance with the applicable standard of care.

TWENTIETH DEFENSE

117. Plaintiff's claims are barred because, based on the state of scientific, medical, and technical knowledge at the time Protonix and Nexium 24HR were marketed, Protonix and Nexium 24HR were reasonably safe for their normal and foreseeable uses at all times, they were not unreasonably dangerous or defective, and their benefits exceeded any associated risks.

TWENTY-FIRST DEFENSE

118. Plaintiff's claims are barred because the methods, standards, and techniques utilized by Pfizer in manufacturing, distributing, marketing, and labeling Protonix and Nexium 24HR and in issuing warnings and instructions with respect to their use, conformed with the generally recognized, reasonably available, and reliable state of knowledge at the time Protonix and Nexium 24HR were manufactured and distributed.

TWENTY-SECOND DEFENSE

119. Plaintiff's claims predicated on state tort law and alleging that Protonix and Nexium 24HR are unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

TWENTY-THIRD DEFENSE

120. Pfizer's conduct, as well as Protonix and Nexium 24HR, conformed with the Federal Food, Drug and Cosmetic Act and the requirements of FDA. Moreover, the activities of Pfizer alleged in the Complaint conformed with all state and federal statutes,

regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

TWENTY-FOURTH DEFENSE

121. Plaintiff's claims are barred, in whole or in part, because Pfizer's advertisements and labeling with respect to Protonix and Nexium 24HR were not false or misleading and, therefore, constitute protected commercial speech under the First Amendment of the United States Constitution.

TWENTY-FIFTH DEFENSE

122. To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Pfizer's rights under the United States Constitution.

TWENTY-SIXTH DEFENSE

123. Should Pfizer be held liable to Plaintiff, which liability is specifically denied, Pfizer would be entitled to a set-off for the total of all amounts paid to that Plaintiff from all collateral sources.

TWENTY-SEVENTH DEFENSE

124. Notwithstanding Plaintiff's claims, Plaintiff received all or substantially all of the benefit from Protonix and Nexium 24HR that Plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Pfizer must be correspondingly reduced.

TWENTY-EIGHTH DEFENSE

125. To the extent applicable, Plaintiff's breach of warranty and other similar claims are barred because there is no privity of contract between Plaintiff and Pfizer;

Plaintiff failed to provide Pfizer with reasonable or adequate notice of the alleged breach of any such purported warranty; Plaintiff did not reasonably rely upon such purported warranty; Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such purported warranty; and/or the purported warranty was appropriately disclaimed, excluded, or modified.

TWENTY-NINTH DEFENSE

126. If Plaintiff sustained the injuries or incurred the expenses alleged, they may have been caused, in whole or in part, by operation of nature or by an act of God or other intervening causes.

THIRTIETH DEFENSE

127. No act or omission of Pfizer was malicious, willful, wanton, reckless, grossly negligent, or intentional and, therefore, any award of punitive damages is barred.

THIRTY-FIRST DEFENSE

128. Plaintiff's claims for punitive damages are in violation of Pfizer's state and federal constitutional rights, including Pfizer's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution and similar provisions of the Constitution, law, public policies, and statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation.

THIRTY-SECOND DEFENSE

129. Plaintiff's claims for punitive damages are in violation of Pfizer's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United

States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; and similar provisions in the Constitution, laws, public policies, and statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation, insofar as such damages are awarded by a jury or other fact-finder that: (a) is not provided with a standard of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (b) is not adequately and clearly instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of Pfizer; (d) is permitted to award punitive damages under a standard for determining liability for such damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and/or (e) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards.

THIRTY-THIRD DEFENSE

130. Plaintiff's claims for punitive damages are in violation of Pfizer's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; and similar provisions in the Constitution, laws, public policies, and

statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation, insofar as such damages are (a) imposed and determined without bifurcating the trial and trying all punitive damages issues only if and after the liability of Pfizer has been found on the merits, and/or (b) imposed and determined based on anything other than Pfizer's conduct in connection with the sale of Protonix and Nexium 24HR, the products alleged in this litigation, or in any other way subjecting Pfizer to impermissible multiple punishments for the same alleged wrong.

THIRTY-FOURTH DEFENSE

131. Plaintiff's claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment f to Section 6, of the Restatement (Third) of Torts: Products Liability.

THIRTY-FIFTH DEFENSE

132. Pfizer is entitled to the benefit of, and hereby claims, all defenses and presumptions available pursuant to any applicable Product Liability Act.

THIRTY-SIXTH DEFENSE

133. Pfizer is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

THIRTY-SEVENTH DEFENSE

134. The Complaint fails to give Pfizer reasonable notice of facts sufficient to complete a choice of law analysis. Subject to this lack of notice (and pending a determination of applicable law), Pfizer reserves the right to assert further or additional

affirmative defenses if it is determined that such defenses exist under applicable state law(s).

THIRTY-EIGHTH DEFENSE

135. Plaintiff's purported allegations of misrepresentation fail to state a claim for which relief may be granted. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

THIRTY-NINTH DEFENSE

136. Plaintiff's claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

FORTIETH DEFENSE

137. Plaintiff's injuries and damages, if any, were the result of an idiosyncratic reaction that Pfizer could not have reasonably foreseen, thereby barring Plaintiff's recovery.

FORTY-FIRST DEFENSE

138. There was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff or reduced the alleged risk, without substantially impairing the usefulness, safety, efficacy, or intended purpose of Protonix and Nexium 24HR, thereby barring Plaintiff's recovery.

FORTY-SECOND DEFENSE

139. This Court lacks personal jurisdiction over Pfizer with respect to Plaintiff's claims.

FORTY-THIRD DEFENSE

140. Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences and the doctrine of economic loss.

FORTY-FOURTH DEFENSE

141. Plaintiff's failure to warn claim is barred given that Pfizer had no duty to warn of risks of which they neither knew nor should have known at the time Protonix and Nexium 24HR were designed, distributed, and manufactured.

FORTY-FIFTH DEFENSE

142. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards and techniques utilized with respect to the design, manufacture, marketing, distribution, and sale of Protonix and Nexium 24HR, including adequate warnings and instructions with respect to the products uses included in the package inserts and other literature conformed to the applicable state of the art. Protonix and Nexium 24HR, including their FDA-approved labeling, complied with the state of scientific and medical knowledge available to Pfizer at the time of their manufacture, distribution, and sale.

FORTY-SIXTH DEFENSE

143. Pfizer denies that the Defendants in the Complaint are the proper parties.

FORTY-SEVENTH DEFENSE

144. Plaintiff's allegations related to fraud do not satisfy the requirements of Ohio Civil Rule 9.

FORTY-EIGHTH DEFENSE

145. Plaintiff knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Complaint. Pursuant to the doctrines of assumption of the risk or informed consent, this conduct bars in whole or in part the damages that Plaintiff seeks to recover herein.

FORTY-NINTH DEFENSE

146. Pfizer reserves the right to supplement this Answer and Affirmative Defenses with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend their answer accordingly.

FIFTIETH DEFENSE

147. Pfizer incorporates by reference each defense asserted by any other Defendant.

WHEREFORE, Pfizer prays for relief and judgment against Plaintiff as follows:

- A. That Plaintiff take nothing by reason of the Complaint;
- B. That this action be dismissed with prejudice;
- C. That Pfizer recover attorneys' fees and costs incurred herein; and
- D. Such further and other relief as the Court deems just and proper.

/s/ Robert A. Pitcairn, Jr.
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Peter J. O'Shea (0086560)
Trial Attorneys for Defendant
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poshea@katzteller.com – Email

JURY DEMAND

Pfizer demands a trial by jury in this action.

/s/ Robert A. Pitcairn, Jr.

Robert A. Pitcairn, Jr.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Answer was served on the following by electronic mail pursuant to Rule 5(B)(2)(f) of the Ohio Rules of Civil Procedure this 8th day of July 2019:

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*Counsel for Abbott Laboratories and
Takeda Defendants*

The undersigned hereby further certifies that a copy of the foregoing Answer was served on the following by regular United States mail pursuant to Rule 5(B)(2)(c) of the Ohio Rules of Civil Procedure this 8th day of July 2019:

Glaxosmithkline Consumer Healthcare
Holdings (US) LLC
184 Liberty Corner Road
Warren, NJ 07059

/s/ Robert A. Pitcairn, Jr.
Robert A. Pitcairn, Jr.

directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint that are directed to other defendants. P&G denies the remaining allegations in paragraph 4 of the Complaint.

5. To the extent the allegations in paragraph 5 of the Complaint are deemed to imply causation of damages, they are denied. P&G admits only that Prilosec OTC is indicated for frequent heartburn (occurring 2 or more times per week). P&G denies all other allegations in paragraph 5 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 5 of the Complaint, and therefore denies those allegations.

PARTIES, JURISDICTION & VENUE

6. The allegations in paragraph 6 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G admits only that plaintiff alleges in this Complaint that the amount in controversy alleged by each plaintiff exceeds the sum of \$25,000 exclusive of interest and costs. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 6 of the Complaint, and therefore denies those allegations.

I. PLAINTIFF

7. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 of the Complaint, including all sub-parts, regarding what plaintiff's residency, plaintiff's alleged use of PPIs, and the conditions plaintiff allegedly was diagnosed with, and therefore denies those allegations. P&G denies all remaining allegations in paragraph 7 of the Complaint.

II. DEFENDANTS

8. The allegations in paragraph 8 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 of the Complaint.

9. The allegations in paragraph 9 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint.

10. The allegations in paragraph 10 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint.

11. The allegations in paragraph 11 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Complaint.

12. The allegations in paragraph 12 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Complaint.

13. The allegations in paragraph 13 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 of the Complaint.

14. The allegations in paragraph 14 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Complaint.

15. The allegations in paragraph 15 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint.

16. The allegations in paragraph 16 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint.

17. The allegations in paragraph 17 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint.

18. The allegations in paragraph 18 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint.

19. The allegations in paragraph 19 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Complaint.

20. The allegations in paragraph 20 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 of the Complaint.

21. The allegations in paragraph 21 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint.

22. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint.

23. The allegations in paragraph 23 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint.

24. P&G admits only that pursuant to a license agreement with AZ and after FDA approval of the product in 2003, it began marketing Prilosec OTC in the United States. P&G denies the remaining allegations in paragraph 24 of the Complaint.

25. P&G admits only that it entered into a license agreement with AZ, that P&G markets Prilosec OTC, and that the license agreement speaks for itself. P&G denies the remaining allegations in paragraph 25 of the Complaint.

26. P&G admits only that it entered into a license agreement with AZ, that P&G markets Prilosec OTC, and that the license agreement speaks for itself. P&G denies the remaining allegations in paragraph 26 of the Complaint.

27. P&G admits only that it entered into a license agreement with AZ, that P&G markets Prilosec OTC, and that the license agreement speaks for itself. P&G denies the remaining allegations in paragraph 27 of the Complaint.

28. P&G admits only that it entered into a license agreement with AZ, that P&G markets Prilosec OTC, and that the license agreement speaks for itself. P&G denies the remaining allegations in paragraph 28 of the Complaint.

29. The allegations in paragraph 29 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint.

30. The allegations in paragraph 30 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Complaint.

31. The allegations in paragraph 31 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 of the Complaint.

32. The allegations in paragraph 32 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32 of the Complaint.

33. The allegations in paragraph 33 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint.

34. The allegations in paragraph 34 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 of the Complaint.

35. The allegations in paragraph 35 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 of the Complaint.

36. The allegations in paragraph 36 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Complaint.

37. The allegations in paragraph 37 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Complaint.

38. The allegations in paragraph 38 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Complaint.

39. The allegations in paragraph 39 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 of the Complaint.

40. The allegations in paragraph 40 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the Complaint.

41. The allegations in paragraph 41 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint.

42. The allegations in paragraph 42 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Complaint.

43. The allegations in paragraph 43 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Complaint.

44. The allegations in paragraph 44 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint.

45. The allegations in paragraph 45 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 of the Complaint.

46. The allegations in paragraph 46 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 of the Complaint.

47. The allegations in paragraph 47 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47 of the Complaint.

48. The allegations in paragraph 48 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Complaint.

49. The allegations in paragraph 49 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 of the Complaint.

50. The allegations in paragraph 50 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 of the Complaint.

51. The allegations in paragraph 51 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the Complaint.

52. The allegations in paragraph 52 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 of the Complaint.

53. The allegations in paragraph 53 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 of the Complaint.

54. P&G admits only that pursuant to a license agreement with AZ and after FDA approval of the product in 2003, it began marketing Prilosec OTC in the United States. P&G denies the remaining allegations in paragraph 54 of the Complaint.

55. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 of the Complaint, and therefore denies those allegations.

56. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 of the Complaint, and therefore denies those allegations.

57. The allegations in paragraph 57 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Complaint.

58. The allegations in paragraph 58 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Complaint.

59. The allegations in paragraph 59 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 of the Complaint.

60. The allegations in paragraph 60 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Complaint.

61. The allegations in paragraph 61 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61 of the Complaint.

62. The allegations in paragraph 62 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 of the Complaint.

63. The allegations in paragraph 63 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 of the Complaint.

64. The allegations in paragraph 64 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Complaint.

65. The allegations in paragraph 65 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65 of the Complaint.

66. The allegations in paragraph 66 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 of the Complaint.

67. The allegations in paragraph 67 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 of the Complaint.

68. The allegations in paragraph 68 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68 of the Complaint.

69. The allegations in paragraph 69 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 of the Complaint.

70. The allegations in paragraph 70 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 of the Complaint.

71. The allegations in paragraph 71 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the Complaint.

72. The allegations in paragraph 72 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 72 of the Complaint.

73. The allegations in paragraph 73 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 73 of the Complaint.

74. The allegations in paragraph 74 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 74 of the Complaint.

75. The allegations in paragraph 75 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 75 of the Complaint.

76. The allegations in paragraph 76 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 of the Complaint.

77. The allegations in paragraph 77 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 77 of the Complaint.

78. The allegations in paragraph 78 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the Complaint.

79. The allegations in paragraph 79 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the Complaint.

80. The allegations in paragraph 80 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 of the Complaint.

81. The allegations in paragraph 81 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 of the Complaint.

82. The allegations in paragraph 82 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 of the Complaint.

83. The allegations in paragraph 83 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the Complaint.

84. The allegations in paragraph 84 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84 of the Complaint.

85. The allegations in paragraph 85 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 of the Complaint.

86. The allegations in paragraph 86 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 of the Complaint.

87. The allegations in paragraph 87 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 of the Complaint.

88. The allegations in paragraph 88 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 of the Complaint.

89. The allegations in paragraph 89 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 89 of the Complaint.

90. The allegations in paragraph 90 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 90 of the Complaint.

91. The allegations in paragraph 91 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 91 of the Complaint.

92. P&G admits that it is an Ohio corporation and has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati.

93. P&G admits that The Procter & Gamble Manufacturing Company is an Ohio corporation and has its principal place of business in Ohio, but denies any remaining allegations in paragraph 93 of the Complaint.

94. P&G admits only that The Procter & Gamble Manufacturing Company is a wholly-owned subsidiary. P&G denies the remaining allegations in paragraph 94 of the Complaint.

95. P&G admits only that plaintiff purports to refer to The Procter & Gamble Manufacturing Company and The Procter & Gamble Company collectively as “Procter & Gamble Defendants”. P&G denies that plaintiff’s collective reference is proper. P&G denies any remaining allegations in paragraph 95 of the Complaint.

96. The allegations in paragraph 96 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 96 of the Complaint that are directed to it and/or to PGM. P&G denies any remaining allegations in paragraph 96 of the Complaint.

97. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 of the Complaint that are directed to the AstraZeneca defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 97 of the Complaint.

98. P&G admits only that it has marketed Prilosec OTC. P&G denies the remaining allegations in paragraph 98 of the Complaint.

99. P&G admits only that pursuant to a license agreement with AZ and after FDA approval of the product in 2003, it began marketing Prilosec OTC in the United States. P&G denies the remaining allegations in paragraph 99 of the Complaint.

100. P&G denies the allegations in paragraph 100 of the Complaint.

101. P&G admits that FDA approved the NDA for Prilosec OTC, NDA 021229, on or about June 20, 2003. P&G denies the remaining allegations in paragraph 101 of the Complaint.

102. P&G admits only that pursuant to a license agreement with AZ, it has marketed Prilosec OTC since 2003. P&G denies the remaining allegations in paragraph 102 of the Complaint.

103. The allegations in paragraph 103 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 103 of the Complaint.

104. P&G denies the allegations in paragraph 104 of the Complaint.

105. P&G denies the allegations in paragraph 105 of the Complaint.

106. The allegations in paragraph 106 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 of the Complaint.

107. The allegations in paragraph 107 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107 of the Complaint.

108. The allegations in paragraph 108 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Complaint.

109. The allegations in paragraph 109 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Complaint.

110. The allegations in paragraph 110 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the Complaint.

111. The allegations in paragraph 111 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 of the Complaint.

112. The allegations in paragraph 112 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 112 of the Complaint.

113. The allegations in paragraph 113 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 of the Complaint.

114. The allegations in paragraph 114 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 of the Complaint.

115. The allegations in paragraph 115 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 of the Complaint.

116. The allegations in paragraph 116 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 of the Complaint.

117. The allegations in paragraph 117 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 of the Complaint.

118. The allegations in paragraph 118 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 of the Complaint.

119. The allegations in paragraph 119 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 of the Complaint.

120. The allegations in paragraph 120 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 120 of the Complaint.

121. The allegations in paragraph 121 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 of the Complaint.

122. The allegations in paragraph 122 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122 of the Complaint.

123. The allegations in paragraph 123 of the Complaint are not directed to P&G, and therefore no response is required of P&G. To the extent a response is required, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 of the Complaint.

124. The allegations in paragraph 124 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 124 of the Complaint.

125. The allegations in paragraph 125 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 125 of the Complaint.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. P&G admits only that Prilosec OTC is indicated for frequent heartburn (occurring 2 or more times per week). P&G denies all other allegations in paragraph 126 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 126 of the Complaint, and therefore denies those allegations.

127. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 127 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 127 of the Complaint.

128. P&G denies any allegations in paragraph 128 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128 of the Complaint, and therefore denies those allegations.

129. P&G denies any allegations in paragraph 129 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 129 of the Complaint, and therefore denies those allegations.

130. P&G denies any allegations in paragraph 130 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 130 of the Complaint, and therefore denies those allegations

131. P&G denies any allegations in paragraph 131 of the Complaint that may be directed to it. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 131 of the Complaint, and therefore denies those allegations.

B. PPI Products Cause Severe Kidney Injuries

132. P&G admits only that an article was published in October 1992 in *The American Journal of Medicine*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 132 of the Complaint.

133. P&G denies the allegations in paragraph 133 of the Complaint.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

134. P&G denies the allegations in paragraph 134 of the Complaint.

135. P&G admits only that publications were made in 2006 in *Kidney International*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized those publications. P&G denies the remaining allegations in paragraph 135 of the Complaint.

136. P&G admits only that an article was published in 2007 in “*Alimentary Pharmacology Therapeutics*” titled “Systematic review: proton pump inhibitor-associated acute interstitial nephritis,” involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the name of the publication or the article. P&G denies the remaining allegations in paragraph 136 of the Complaint.

137. P&G admits only that an article was published in February 2007 in the *British Journal of Clinical Pharmacology* titled “Proton pump inhibitor-induced acute interstitial nephritis,” involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 137 of the Complaint.

138. P&G admits only that Public Citizen filed a petition on or about August 23, 2011, with FDA, but denies that plaintiff has completely or accurately characterized the petition. P&G denies the remaining allegations in paragraph 138 of the Complaint.

139. P&G admits only that Public Citizen filed a petition on or about August 23, 2011, with FDA, but denies that plaintiff has completely or accurately characterized the petition. P&G denies the remaining allegations in paragraph 139 of the Complaint.

140. P&G admits only that FDA responded to the August 23, 2011 petition filed by Public Citizen, but denies that plaintiff has completely or accurately characterized FDA's response. P&G denies the remaining allegations in paragraph 140 of the Complaint.

141. P&G admits only that FDA responded to the August 23, 2011 petition filed by Public Citizen, but denies that plaintiff has completely or accurately characterized FDA's response. P&G denies the remaining allegations in paragraph 141 of the Complaint.

142. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Complaint, and therefore denies those allegations.

143. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 143 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 143 of the Complaint are directed to P&G, P&G admits that FDA has concluded over-the-counter PPIs, such as Prilosec OTC, should not contain a warning regarding AIN. P&G denies the remaining allegations in paragraph 143 of the Complaint.

144. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 144 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 144 of the Complaint.

145. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 145 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 145 of the Complaint.

146. P&G denies the allegations in paragraph 146 of the Complaint.

147. P&G denies any allegations in paragraph 147 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 147 of the Complaint, and therefore denies those allegations.

148. P&G denies the allegations in paragraph 148 of the Complaint, including all sub-parts.

149. P&G denies any allegations in paragraph 149 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 149 of the Complaint, and therefore denies those allegations.

150. P&G denies any allegations in paragraph 150 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 150 of the Complaint, and therefore denies those allegations.

151. P&G denies any allegations in paragraph 151 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 151 of the Complaint, and therefore denies those allegations.

ii. PPI-Induced Acute Kidney Injury (“AKI”)

152. P&G denies any allegations in paragraph 152 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G denies the remaining allegations in paragraph 152 of the Complaint.

153. P&G denies the allegations in paragraph 153 of the Complaint.

154. P&G denies the allegations in paragraph 154 of the Complaint.

155. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 155 of the Complaint are directed at P&G, P&G admits that FDA has concluded over-the-counter PPIs, namely Prilosec OTC, should not contain a warning regarding AIN. P&G denies the remaining allegations in paragraph 155 of the Complaint.

156. P&G denies any allegations in paragraph 156 of the Complaint that may be directed to it or that are deemed to imply causation of injury. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 156 of the Complaint, and therefore denies those allegations.

ii. PPI-Induced Chronic Kidney Disease (“CKD”)

157. To the extent the allegations in paragraph 157 of the Complaint are deemed to imply causation of injury, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 157 of the Complaint, and therefore denies those allegations.

158. To the extent the allegations in paragraph 158 of the Complaint are deemed to imply causation of injury, they are denied. P&G is without knowledge or information sufficient to form

a belief as to the truth of the remaining allegations in paragraph 158 of the Complaint, and therefore denies those allegations.

159. P&G denies the allegations in paragraph 159 of the Complaint.

160. P&G admits only that an article was published in February 2016 in the *Journal of the American Society of Nephrology*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 160 of the Complaint.

161. P&G admits only that an article was published in April 2016 in the *Journal of Nephrology*, involving certain kidney conditions, but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 161 of the Complaint.

162. To the extent the allegations in paragraph 162 of the Complaint are deemed to imply causation of injury, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 162 of the Complaint, and therefore denies those allegations.

163. P&G admits Xie, Yan, et al., published an article “Long-term kidney outcomes among users of proton pump inhibitors without intervening acute kidney injury,” but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 163 of the Complaint.

164. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 164 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 164 of the Complaint.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. To the extent the allegations in paragraph 165 of the Complaint are directed to P&G or are deemed to imply causation of injury, they are denied. P&G denies the remaining allegations in paragraph 165 of the Complaint.

166. To the extent the allegations in paragraph 166 of the Complaint are directed to P&G or are deemed to imply causation of injury, they are denied. P&G denies the remaining allegations in paragraph 166 of the Complaint.

167. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 167 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 167 of the Complaint.

168. To the extent the allegations in paragraph 168 of the Complaint are directed to P&G or are deemed to imply causation of injury, they are denied. P&G denies the remaining allegations in paragraph 168 of the Complaint.

169. P&G denies the allegations in paragraph 169 of the Complaint.

170. P&G denies the allegations in paragraph 170 of the Complaint.

171. To the extent the allegations in paragraph 171 of the Complaint are directed to P&G or are deemed to imply causation of injury, they are denied. P&G denies the remaining allegations in paragraph 171 of the Complaint.

172. P&G denies the allegations in paragraph 172 of the Complaint.

173. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 of the Complaint that are directed to other defendants or

products, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 173 of the Complaint.

D. Safer Alternatives to PPIs

174. To the extent the allegations in paragraph 174 of the Complaint are deemed to imply causation of damages, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 174 of the Complaint.

175. P&G admits D. Marks published an article “Time to halt the overprescribing of proton pump inhibitor therapy,” but denies that plaintiff has completely or accurately characterized the article. P&G denies the remaining allegations in paragraph 175 of the Complaint

176. To the extent the allegations in paragraph 176 of the Complaint are deemed to imply causation of damages, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 176 of the Complaint.

E. Injuries Resulting from PPI Products

177. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 177 of the Complaint.

178. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 178 of the Complaint.

179. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 179 of the Complaint.

180. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 180 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 180 of the Complaint.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

181. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 181 of the Complaint.

182. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 182 of the Complaint.

183. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 183 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 183 of the Complaint.

184. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 184 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 184 of the Complaint.

185. The allegations in paragraph 185 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 185 of the Complaint, and therefore denies those allegations.

186. The allegations in paragraph 186 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 186 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 186 of the Complaint.

187. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 187 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 187 of the Complaint.

188. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 188 the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 188 of the Complaint.

189. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 189 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 189 of the Complaint.

190. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 190 of the Complaint.

191. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 191 of the Complaint.

192. To the extent the allegations in paragraph 192 of the Complaint are deemed to imply causation of injury or damages, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 192 of the Complaint are directed at P&G, P&G states that FDA has concluded over-the-counter PPIs, namely Prilosec OTC, should not contain a warning regarding AIN. P&G denies the remaining allegations in paragraph 192 of the Complaint.

193. To the extent the allegations in paragraph 193 of the Complaint are deemed to imply causation of damages or injury, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 193 of the Complaint that

are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 193 of the Complaint.

194. To the extent the allegations in paragraph 194 of the Complaint are deemed to imply causation of damages or injury, they are denied. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 194 of the Complaint.

195. The allegations in paragraph 195 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 195 of the Complaint.

G. Defendants Violation of Federal Law

196. The allegations in paragraph 196 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 196 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 196 of the Complaint.

197. The allegations in paragraph 197 of the Complaint, including all sub-parts, are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 197 of the Complaint, including all sub-parts,

that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 197 of the Complaint, including all sub-parts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. P&G incorporates its responses to paragraphs 1 through 197 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 198 of the Complaint.

199. The allegations in paragraph 199 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 199 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 199 of the Complaint.

200. The allegations in paragraph 200 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 200 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 200 of the Complaint.

201. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 201 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 201 of the Complaint.

202. The allegations in paragraph 202 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or

necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 202 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 202 of the Complaint.

203. The allegations in paragraph 203 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 203 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 203 of the Complaint.

204. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 204 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 204 of the Complaint.

205. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 205 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 205 of the Complaint.

206. P&G denies the allegations in paragraph 206 of the Complaint.

207. P&G is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in paragraph 207 of the Complaint about what plaintiff's doctors allegedly said to plaintiff, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 207 of the Complaint.

208. P&G denies the allegations in paragraph 208 of the Complaint.

209. To the extent the allegations in paragraph 209 of the Complaint are allegations of conclusions of law, no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 209 of the Complaint.

210. To the extent the allegations in paragraph 210 of the Complaint are allegations of conclusions of law, no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 210 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 210 of the Complaint.

211. P&G is without knowledge or information sufficient at this time to form a belief as to the truth of the allegations in paragraph 211 of the Complaint about conversations plaintiff may have had with their doctors, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 211 of the Complaint.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

212. P&G incorporates its responses to paragraphs 1 through 211 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 212 of the Complaint.

213. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 213 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 213 of the Complaint.

214. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 214 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 214 of the Complaint.

215. P&G admits only that it marketed Prilosec OTC, but P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215 of the Complaint about what products the plaintiff used, and therefore denies those allegations. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 215 of the Complaint.

216. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 216 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 216 of the Complaint.

217. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 217 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 217 of the Complaint.

218. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 218 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 218 of the Complaint.

219. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 219 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 219 of the Complaint.

220. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 220 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 220 of the Complaint.

221. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 221 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 221 of the Complaint.

222. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 222 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 222 of the Complaint.

223. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 223 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 223 of the Complaint.

224. The allegations in paragraph 224 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 224 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 224 of the Complaint.

225. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 225 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 225 of the Complaint.

226. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 226 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 226 of the Complaint.

227. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 227 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 227 of the Complaint.

228. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 228 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 228 of the Complaint.

229. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 229 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 229 of the Complaint.

230. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 230 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 230 of the Complaint.

231. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 231 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 231 of the Complaint.

232. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 232 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 232 of the Complaint.

233. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 233 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 233 of the Complaint.

234. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 234 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 234 of the Complaint.

235. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 235 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 235 of the Complaint.

236. P&G denies the allegations in paragraph 236 of the Complaint.

237. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 237 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 237 of the Complaint, including all sub-parts.

238. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 238 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 238 of the Complaint.

239. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 239 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 239 of the Complaint.

240. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 240 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 240 of the Complaint.

241. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 241 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 241 of the Complaint.

242. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 242 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 242 of the Complaint.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

243. P&G incorporates its responses to paragraphs 1 through 242 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 243 of the Complaint.

244. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 244 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 244 of the Complaint.

245. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 245 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 245 of the Complaint.

246. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 246 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 246 of the Complaint.

247. P&G denies the allegations in paragraph 247 of the Complaint.

248. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 248 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 248 of the Complaint.

249. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 249 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 249 of the Complaint.

250. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 250 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 250 of the Complaint.

251. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 251 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 251 of the Complaint.

252. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 252 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 252 of the Complaint.

253. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 253 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 253 of the Complaint.

254. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 254 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 254 of the Complaint.

255. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 255 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 255 of the Complaint.

256. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 256 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 256 of the Complaint.

257. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 257 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 257 of the Complaint, including all sub-parts.

258. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 258 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 258 of the Complaint.

259. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 259 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 259 of the Complaint.

260. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 260 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 260 of the Complaint.

261. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 261 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 261 of the Complaint.

262. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 262 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 262 of the Complaint.

263. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 263 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 263 of the Complaint.

264. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 264 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 264 of the Complaint.

265. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 265 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 265 of the Complaint.

266. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 266 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 266 of the Complaint.

267. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 267 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 267 of the Complaint.

268. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 268 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 268 of the Complaint.

269. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 269 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 269 of the Complaint.

270. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 270 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 270 of the Complaint.

271. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 271 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 271 of the Complaint.

272. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 272 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 272 of the Complaint.

273. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 273 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 273 of the Complaint.

274. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 274 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 274 of the Complaint.

275. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 275 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 275 of the Complaint.

276. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 276 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 276 of the Complaint.

277. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 277 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 277 of the Complaint.

278. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 278 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 278 of the Complaint.

279. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 279 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 279 of the Complaint.

280. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 280 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 280 of the Complaint.

281. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 281 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 281 of the Complaint.

282. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 282 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 282 of the Complaint.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. P&G incorporates its responses to paragraphs 1 through 282 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 283 of the Complaint.

284. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 284 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 284 of the Complaint.

285. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 285 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 285 of the Complaint.

286. The allegations in paragraph 286 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 286 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 286 of the Complaint.

287. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 287 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 287 of the Complaint.

288. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 288 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 288 of the Complaint.

289. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 289 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 289 of the Complaint.

290. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 290 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 290 of the Complaint.

291. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 291 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 291 of the Complaint.

292. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 292 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 292 of the Complaint.

293. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 293 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 293 of the Complaint.

294. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 294 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 294 of the Complaint.

295. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 295 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 295 of the Complaint.

296. The allegations in paragraph 296 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 296 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 296 of the Complaint.

297. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 297 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 297 of the Complaint.

298. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 298 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 298 of the Complaint.

299. The allegations in paragraph 299 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 299 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 299 of the Complaint.

300. P&G without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 300 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 300 of the Complaint.

301. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 301 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 301 of the Complaint.

302. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 302 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 302 of the Complaint.

303. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 303 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 303 of the Complaint.

304. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 304 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 304 of the Complaint.

305. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 305 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 305 of the Complaint.

306. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 306 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 306 of the Complaint.

307. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 307 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 307 of the Complaint.

308. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 308 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 308 of the Complaint.

309. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 309 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 309 of the Complaint.

310. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 310 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 310 of the Complaint.

311. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 311 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 311 of the Complaint.

312. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 312 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 312 of the Complaint.

COUNT IV
NEGLIGENCE

313. P&G incorporates its responses to paragraphs 1 through 312 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 313 of the Complaint.

314. The allegations in paragraph 314 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 314 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 314 of the Complaint.

315. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 315 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 315 of the Complaint.

316. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 316 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 316 of the Complaint, including all sub-parts.

317. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 317 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 317 of the Complaint.

318. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 318 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 318 of the Complaint.

319. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 319 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 319 of the Complaint.

320. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 320 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 320 of the Complaint.

321. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 321 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 321 of the Complaint.

322. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 322 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 322 of the Complaint.

323. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 323 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 323 of the Complaint.

324. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 324 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 324 of the Complaint.

325. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 325 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 325 of the Complaint.

326. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 326 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 326 of the Complaint.

COUNT V
NEGLIGENCE PER SE

327. P&G incorporates its responses to paragraphs 1 through 326 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 327 of the Complaint.

328. The allegations in paragraph 328 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 328 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 328 of the Complaint.

329. The allegations in paragraph 329 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 329 of the Complaint.

330. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 330 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 330 of the Complaint.

331. The allegations in paragraph 331 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 331 of the Complaint.

332. The allegations in paragraph 332 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G denies the allegations in paragraph 332 of the Complaint.

333. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 333 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 333 of the Complaint.

334. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 334 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 334 of the Complaint.

COUNT VI
NEGLIGENCE—FAILURE TO TEST

335. P&G incorporates its responses to paragraphs 1 through 334 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 335 of the Complaint.

336. The allegations in paragraph 336 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or

necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 336 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 336 of the Complaint.

337. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 337 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 337 of the Complaint.

338. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 338 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 338 of the Complaint.

339. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 339 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 339 of the Complaint.

340. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 340 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 340 of the Complaint.

341. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 341 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 341 of the Complaint.

342. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 342 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 342 of the Complaint.

343. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 343 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 343 of the Complaint.

344. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 344 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 344 of the Complaint.

345. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 345 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 345 of the Complaint.

346. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 346 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 346 of the Complaint.

COUNT VII

**STRICT PRODUCTS LIABILITY DUE TO NONCONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77**

347. P&G incorporates its responses to paragraphs 1 through 346 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 347 of the Complaint.

348. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 348 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 348 of the Complaint.

349. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 349 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 349 of the Complaint.

350. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 350 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 350 of the Complaint.

351. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 351 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 351 of the Complaint.

352. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 352 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 352 of the Complaint.

353. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 353 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 353 of the Complaint.

354. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 354 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 354 of the Complaint.

355. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 355 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 355 of the Complaint.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. P&G incorporates its responses to paragraphs 1 through 355 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 356 of the Complaint.

357. The allegations in paragraph 357 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 357 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 357 of the Complaint.

358. The allegations in paragraph 358 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or

necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 358 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 358 of the Complaint.

359. The allegations in paragraph 359 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 359 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 359 of the Complaint.

360. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 360 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 360 of the Complaint.

361. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 361 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 361 of the Complaint.

362. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 362 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 362 of the Complaint.

363. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 363 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 363 of the Complaint.

364. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 364 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 364 of the Complaint, including all sub-parts.

365. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 365 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 365 of the Complaint.

366. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 366 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 366 of the Complaint.

367. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 367 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 367 of the Complaint.

368. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 368 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 368 of the Complaint.

369. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 369 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 369 of the Complaint.

370. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 370 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 370 of the Complaint.

371. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 371 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 371 of the Complaint.

372. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 372 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 372 of the Complaint.

373. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 373 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 373 of the Complaint.

374. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 374 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 374 of the Complaint.

375. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 375 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 375 of the Complaint.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. P&G incorporates its responses to paragraphs 1 through 375 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 376 of the Complaint.

377. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 377 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 377 of the Complaint.

378. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 378 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 378 of the Complaint.

379. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 379 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 379 of the Complaint.

380. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 380 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 380 of the Complaint.

381. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 381 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 381 of the Complaint.

382. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 382 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 382 of the Complaint.

383. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 383 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 383 of the Complaint.

384. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 384 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 384 of the Complaint.

385. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 385 of the Complaint with respect to plaintiff's "skills" or

allegations that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 385 of the Complaint.

386. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 386 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 386 of the Complaint.

387. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 387 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 387 of the Complaint.

388. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 388 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 388 of the Complaint.

389. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 389 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 389 of the Complaint.

COUNT X
NEGLIGENT MISREPRESENTATION

390. P&G incorporates its responses to paragraphs 1 through 389 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 390 of the Complaint.

391. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 391 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 391 of the Complaint.

392. The allegations in paragraph 392 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 392 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 392 of the Complaint.

393. The allegations in paragraph 393 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 393 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 393 of the Complaint.

394. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 394 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 394 of the Complaint.

395. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 395 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 395 of the Complaint.

396. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 396 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 396 of the Complaint.

397. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 397 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 397 of the Complaint.

398. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 398 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 398 of the Complaint.

399. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 399 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 399 of the Complaint.

400. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 400 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 400 of the Complaint.

COUNT IX
FRAUD AND FRAUDULENT MISREPRESENTATION

401. P&G incorporates its responses to paragraphs 1 through 400 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 401 of the Complaint.

402. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 402 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 402 of the Complaint.

403. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 403 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 403 of the Complaint.

404. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 404 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 404 of the Complaint.

405. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 405 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 405 of the Complaint.

406. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 406 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 406 of the Complaint.

407. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 407 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 407 of the Complaint.

408. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 408 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 408 of the Complaint.

409. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 409 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 409 of the Complaint.

410. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 410 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 410 of the Complaint.

411. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 411 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 411 of the Complaint.

412. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 412 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 412 of the Complaint.

413. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 413 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 413 of the Complaint.

COUNT XII
GROSS NEGLIGENCE

414. P&G incorporates its responses to paragraphs 1 through 413 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 414 of the Complaint.

415. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 415 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 415 of the Complaint, including all sub-parts.

416. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 416 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 416 of the Complaint.

COUNT XIII
FRAUDULENT CONCEALMENT

417. P&G incorporates its responses to paragraphs 1 through 416 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 417 of the Complaint.

418. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 418 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 418 of the Complaint.

419. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 419 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 419 of the Complaint.

420. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 420 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 420 of the Complaint.

421. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 421 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 421 of the Complaint.

422. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 422 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 422 of the Complaint.

423. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 423 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 423 of the Complaint.

424. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 424 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 424 of the Complaint.

425. The allegations in paragraph 425 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 425 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 425 of the Complaint.

426. The allegations in paragraph 426 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 426 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 426 of the Complaint.

427. The allegations in paragraph 427 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 427 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 427 of the Complaint.

428. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 428 of the Complaint that are directed to other defendants, and

therefore denies those allegations. P&G denies the remaining allegations in paragraph 428 of the Complaint.

429. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 429 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 429 of the Complaint.

430. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 430 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 430 of the Complaint.

431. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 431 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 431 of the Complaint.

432. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 432 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G specifically denies making any knowingly and intentionally false and misleading statements regarding Prilosec OTC and denies the remaining allegations in paragraph 432 of the Complaint.

433. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 433 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies having maliciously or intentionally concealed

material information from plaintiff and/or plaintiff's healthcare providers regarding Prilosec OTC and further denies the remaining allegations in paragraph 433 of the Complaint.

434. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 434 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 434 of the Complaint.

435. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 435 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 435 of the Complaint.

436. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 436 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 436 of the Complaint.

437. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 437 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 437 of the Complaint.

438. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 438 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies that it concealed any hazards associated with Prilosec OTC use and further denies the remaining allegations in paragraph 438 of the Complaint.

439. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 439 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 439 of the Complaint.

440. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 440 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 440 of the Complaint.

441. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 441 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 441 of the Complaint.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. P&G incorporates its responses to paragraphs 1 through 441 above as if fully set forth herein. P&G denies the remaining allegations in paragraph 442 of the Complaint.

443. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 443 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 443 of the Complaint.

444. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 444 of the Complaint, including all sub-parts, that are directed to

other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 444 of the Complaint, including all sub-parts.

445. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 445 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 445 of the Complaint.

446. P&G is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 446 of the Complaint that are directed to other defendants, and therefore denies those allegations. P&G denies the remaining allegations in paragraph 446 of the Complaint.

447. To the extent demands or statements in the “Wherefore” paragraphs of the Complaint are directed to P&G or are deemed to be allegations or other statements that P&G is liable to plaintiff, they are denied, and P&G specifically denies that plaintiff is entitled to any relief whatsoever.

448. P&G denies any and all allegations or other statements contained in headings and captions of the Complaint.

449. P&G denies any and all allegations or statements in the Complaint except those that P&G has expressly admitted in its answer to this Complaint.

DEFENSES

By asserting these defenses, P&G does not admit that it has the burden of proof or persuasion with respect to any of these defenses. Subject to further investigation and without waiving any additional defenses, P&G asserts the following defenses:

1. Plaintiff’s Complaint fails to state a claim upon which relief can be granted.

2. Plaintiff's Complaint should be dismissed and/or transferred for lack of venue and/or on the grounds of *forum non conveniens*.

3. P&G asserts any and all defenses of lack of personal jurisdiction that are now or may become applicable in any plaintiff's case.

4. Plaintiff's claims may be barred because of plaintiff's failure to join necessary and indispensable parties.

5. Plaintiff's claims may be barred, in whole or in part, by the doctrines of release, estoppel, accord and satisfaction, unclean hands, res judicata, laches, and/or waiver.

6. Plaintiff's claims are barred, in whole or in part, because plaintiff lacks standing or capacity to bring such claims and/or is not the real party in interest.

7. Plaintiff's claims are barred, in whole or in part, because Prilosec OTC is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and plaintiff's claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with determinations by the FDA specifying the language that should be used in the labeling accompanying Prilosec OTC. Accordingly, plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

8. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and P&G hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

9. P&G hereby pleads all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22 – 2307.29.

10. P&G asserts and incorporates all defenses, offsets, and remedies for contribution under Ohio Rev. Code §§ 2307.25 – 2307.26.

11. Plaintiff's claims are barred because Prilosec OTC is an "ethical drug" as defined by Ohio Rev. Code Ann. § 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of Prilosec OTC.

12. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory principles set forth in Ohio Rev. Code Ann. §§ 2315.32– 2315.36.

13. Plaintiff's recovery as against P&G should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.

14. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.

15. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

16. Plaintiff's Complaint fails to state a claim for unlawful conduct or for false or misleading business practices under Ohio Rev. Code Ann. §§ 1345.01, *et seq.*

17. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

18. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

19. Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. §1345.12(C), specifically precludes claims for personal injury.

20. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Rev. Code Ann. § 2307.711.

21. All or part of the injuries or damages alleged in plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct P&G had no reason to anticipate and for whose conduct P&G is not and were not responsible. Ohio Rev. Code Ann. § 2307.22, *et seq.*

22. The injuries or damages of which plaintiff complains were caused or contributed to by one or more persons from whom the plaintiff do not seek recovery in this action. Ohio Rev. Code Ann. § 2307.23.

23. One or more of plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Rev. Code Ann. §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, *et al.*

24. Plaintiff's claims are barred, in whole or in part, because P&G exercised reasonable care, acted in good faith, and gave adequate warnings of all known or reasonably knowable risks associated with the use of Prilosec OTC at all relevant times. *See* Ohio Rev. Code Ann. § 2307.76(A) & (B).

25. Plaintiff's claims are barred by the learned intermediary doctrine, as codified by Ohio Rev. Code Ann. § 2307.76(C).

26. Plaintiff's design defect claims fail under Ohio Rev. Code Ann. § 2307.75(D) because adequate warning and instruction were provided under Ohio Rev. Code Ann. § 2307.76 concerning any unavoidably unsafe aspects of the product.

27. Plaintiff's design defect claims fail under Ohio Rev. Code Ann. § 2307.75(E) because the alleged risk of which plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

28. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Rev. Code Ann. § 2307.75(F).

29. Prilosec OTC complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of these products, and that they were neither defective nor unreasonably dangerous.

30. P&G, at all times, used reasonable care, skill, and diligence, and complied with generally accepted standards in the industry.

31. Prilosec OTC complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States or by applicable state law, or by any agency of the United States or applicable state.

32. Plaintiff's inadequate warning claims are barred under Ohio Rev. Code Ann. § 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

33. Plaintiff's claims for punitive or exemplary damages as set forth in the Complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).

34. To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and its progeny.

35. Plaintiff's fraud-based claims may be barred, in whole or in part, because plaintiff did not rely to their detriment upon any statement by P&G in deciding to use Prilosec OTC.

36. P&G is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any applicable law, rule of law, or governing statute of any state, including but not limited to any relevant product liability acts and/or consumer fraud and/or unfair competition acts, that would bar or otherwise limit any of the claims asserted by plaintiff.

37. Plaintiff's claims may be barred by the doctrine(s) contained in Restatement (Second) of Torts § 402A, and comments thereto, including but not limited to comments j and k, and/or Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

38. The benefits and utility of Prilosec OTC outweigh the risk of danger or harm, if any, inherent in the product.

39. Plaintiff's claims may be barred, in whole or in part, by misuse or unintended use of Prilosec OTC.

40. Plaintiff's claims may be barred because plaintiff's injuries, if any, were caused, in whole or in part, by the intervening or superseding conduct of plaintiff, independent third parties,

or events that were extraordinary under the circumstances, not foreseeable in the normal course, or independent of or far removed from P&G's conduct or control.

41. Plaintiff's claims may be barred, in whole or in part, because plaintiff provided learned or informed consent to the use of Prilosec OTC.

42. Plaintiff's claims may be barred, in whole or in part, by the negligent and/or otherwise wrongful conduct of others, constituting an intervening or superseding cause of the alleged harm.

43. Plaintiff's claims may be barred, in whole or in part, by applicable statutes of limitations and/or repose.

44. Plaintiff's claims may be barred by prescription.

45. To the extent plaintiff assert claims for breach of express or implied warranty, plaintiff lack the requisite privity with P&G to maintain such claims.

46. To the extent plaintiff assert claims for breach of express or implied warranty, such claims are barred because plaintiff did not reasonably rely upon any alleged express or implied warranty, and because plaintiff did not give P&G adequate notice of any alleged breach of warranty, express or implied.

47. Plaintiff's have no right to assert a claim that P&G's product is unreasonably dangerous because of nonconformity to an express warranty because plaintiff can neither prove the existence of such an explicit warranty nor any causal relationship between an express warranty, if one was communicated to plaintiff, and plaintiff's alleged damage.

48. To the extent that plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

49. To the extent plaintiff seek recovery of punitive or exemplary damages against P&G, any such damages are barred and/or limited by applicable laws and/or standards of proof.

50. Plaintiff's claims for punitive damages cannot be sustained because an award of punitive damages by a jury that is not specifically instructed on the size, guidelines, or limits of punitive damages imposed and provided a sufficient clarity for determining such an award, not subject to judicial review on the basis of an objective standard, is arbitrary and capricious, and would violate due process and the equal protection rights guaranteed by the Fourteenth Amendment of the United States Constitution and the double jeopardy clause of the Fifth Amendment and corresponding provisions of the Constitution of any state whose law is deemed to apply in this case.

51. Plaintiff's claims for punitive damages are barred and are in violation of the due process of law clause of the Fifth and Fourteenth Amendments to the United States Constitution, and are in violation of the prohibition of *ex post facto* laws contained in Section 10, Paragraph 1 of Article 1 of the United States Constitution.

52. Any civil penalties and remedies sought by plaintiff are unconstitutional and barred as excessive fines or penalties prohibited under the Eighth and Fourteenth Amendments to the United States Constitution.

53. To the extent plaintiff seek recovery of punitive, exemplary or aggravated damages against P&G, any such claims are in violation of and are barred by the Constitution of the United States and any relevant comparable state constitutional provisions, including but not limited to, the Due-Process and Equal Protection Clauses contained in the Fifth and Fourteenth Amendments; the Excessive Fines Clause of the Eighth Amendment; and the Tenth Amendment.

54. To the extent that plaintiff seeks punitive, exemplary, or aggravated damages, P&G specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and cases subsequent to *BMW*, including *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007).

55. Punitive damages, if any, must be apportioned among all potentially responsible parties and nonparties. The true identity of all such potentially responsible nonparties is not presently known to P&G. P&G reserves the right to supplement.

56. Plaintiff's claims are barred to the extent the injuries alleged in the Complaint, and/or any applicable individual complaint, were idiopathic in nature or caused or enhanced by preexisting or unrelated medical, genetic, environmental, or psychiatric conditions, diseases, or illnesses, by plaintiff's own idiosyncratic reactions to the product(s), and/or by operation of nature.

57. If plaintiff sustained the injuries or damages alleged, they were caused, in whole or in part, by operation of nature or by act of God.

58. Plaintiff's damages, if any, may be limited, in whole or in part, by plaintiff's failure to mitigate.

59. Plaintiff's claim that P&G's product was unreasonably dangerous because of an inadequate warning fails because P&G owed plaintiff no warning at all given that plaintiff already knew or reasonably should have been expected to know of the characteristic of the product that could cause damage and the danger thereof.

60. Any injuries or damages sustained by plaintiff were directly and proximately caused by failure of plaintiff to heed warnings and instructions.

61. Plaintiff's claims are barred because there is no evidence that plaintiff's health care providers would have heeded any different warnings than those provided.

62. At all times, Prilosec OTC was distributed and/or sold in compliance with all applicable federal, state and local laws and regulations, and rules promulgated and enforced by the FDA.

63. Prilosec OTC is and was formulated, tested, manufactured, distributed, and labeled in accordance with the provisions of the federal Food Drug and Cosmetic Act and the regulations promulgated pursuant thereto.

64. Any communications and/or actions between any defendant and the FDA and/or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

65. Plaintiff's claims are barred, in whole or in part, because commercial speech relating to the subject product is protected under the First Amendment of the United States Constitution and the applicable state constitution.

66. At the time the alleged product would have left this defendant's control, it did not know, and, in light of then-existing reasonably available scientific and technical knowledge, it could not have known of the characteristic that allegedly caused the damage alleged in the Complaint, and/or applicable individual complaint, or the danger of such characteristic. To the contrary, reasonably available scientific and technical knowledge indicates that if the alleged product of this defendant is used as directed, there is no appreciable possibility that the product will cause the damage herein alleged.

67. The product allegedly involved in this action was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused, or contributed to, plaintiff's alleged damages, if any.

68. P&G had no duty to warn about any possible dangers that were not known at the time of manufacture and sale of the product in question.

69. Prilosec OTC, when properly used, is and was safe and fit for its intended use and purpose at all relevant times.

70. P&G's actions, if any, and Prilosec OTC conformed to the state of the art and the trade and custom in the industry as they existed at the time.

71. Plaintiff are barred, in whole or in part, from recovery due to spoliation of evidence.

72. To the extent that any medical or hospital expenses claimed by plaintiff have been, or will be, indemnified in whole or in part, from any collateral source, any verdict or judgment against defendant must be reduced by those amounts pursuant to applicable state law.

73. To the extent that any or all of plaintiff's claims have been settled, compromised, or otherwise discharged, a set-off is due. P&G avails itself of each and every set-off or defense available under applicable state law.

74. The claims against P&G, separately and severally, are barred by the Commerce Clause of the United States Constitution because they would, if allowed, impose an undue burden on interstate commerce.

75. P&G adopts and relies upon all provisions and defenses afforded it under the United States Constitution and any applicable state constitution(s).

76. P&G claims the benefits of any disclaimers and/or limitations on its liability made to anyone involved in the manufacture, distribution, or sale of Prilosec OTC.

77. To the extent applicable, P&G asserts and preserves all claims for indemnification and/or contribution from any person and/or entity whose negligence or other fault contributed to plaintiff's alleged injuries and damages.

78. Plaintiff's claims may be barred because plaintiff has failed to comply with conditions precedent necessary to bring this action and/or each particular cause of action asserted by plaintiff.

79. Plaintiff's claims are barred, in whole or in part, by the laws of other jurisdictions.

80. To the extent plaintiff has attempted to plead any common law claims, such claims are preempted, superseded, and/or subsumed by applicable state law.

81. With respect to each and every purported cause of action, the acts of P&G, if any, were at all times done in good faith and without malice.

82. P&G incorporates all defenses available to it under any applicable law.

83. P&G incorporates the defenses of all others who are or may become parties to this action as if fully set forth herein.

84. P&G reserves the right to amend its answer to add additional defenses and/or averments as additional information becomes available.

WHEREFORE, PREMISES CONSIDERED, The Procter & Gamble Company, respectfully prays for the following relief:

1. That judgment be entered in its favor, dismissing the Complaint, and/or any applicable individual complaint, in its entirety with prejudice.

2. That judgment be entered in its favor for costs incurred in connection with this matter; and

3. That this Court grant it such other and further relief, both at law and in equity, whether general or special, to which it may be justly entitled.

JURY DEMAND

Now comes The Procter & Gamble Company, and files this JURY DEMAND and requests a trial by jury in each and every case.

Respectfully Submitted,

/s/ Emily S. Prem

Emily S. Prem (0093988)

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Counsel for Defendant The Procter & Gamble Company

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing document was served this 23rd day of July, 2019 by United States First Class Mail, postage prepaid, upon the following:

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/s/ Emily S. Prem

**IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A. BEHYMER

Plaintiff,

VS.

ABBOTT LABORATORIES, *et al.*

Case No. A 1902638

Judge:

**ANSWER OF DEFENDANT THE PROCTER & GAMBLE MANUFACTURING
COMPANY TO PLAINTIFF'S COMPLAINT AND JURY DEMAND**

Defendant The Procter & Gamble Manufacturing Company (“PGM”) answers plaintiff’s Complaint (“Complaint”), and states as follows:

1. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint based on plaintiff's personal knowledge and belief, and therefore denies those allegations. PGM denies all remaining allegations in paragraph 1 of the Complaint.

2. The allegations in paragraph 2 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies all allegations in paragraph 2 of the Complaint.

3. PGM denies the allegations in paragraph 3 of the Complaint.

4. PGM admits only that plaintiff purports to bring “personal injury action”; that Prilosec OTC is within a class of medications known as proton pump inhibitors; and that proton pump inhibitors have been referred to as “PPIs.” Further, PGM admits it packages Prilosec OTC. PGM denies all other allegations in paragraph 4 of the Complaint that are directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations.



paragraph 4 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 4 of the Complaint.

5. To the extent the allegations in paragraph 5 of the Complaint are deemed to imply causation of damages, they are denied. PGM admits only that Prilosec OTC is indicated for frequent heartburn (occurring 2 or more times per week). PGM denies all other allegations in paragraph 5 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 5 of the Complaint, and therefore denies those allegations.

PARTIES, JURISDICTION & VENUE

6. The allegations in paragraph 6 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM admits only that plaintiff alleges in this Complaint that the amount in controversy alleged by each plaintiff exceeds the sum of \$25,000 exclusive of interest and costs. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 6 of the Complaint, and therefore denies those allegations.

I. PLAINTIFF

7. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 of the Complaint, including all sub-parts, regarding what plaintiff's residency, plaintiff's alleged use of PPIs, and the conditions plaintiff allegedly was diagnosed with, and therefore denies those allegations. PGM denies all remaining allegations in paragraph 7 of the Complaint.

II. DEFENDANTS

8. The allegations in paragraph 8 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 of the Complaint.

9. The allegations in paragraph 9 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint.

10. The allegations in paragraph 10 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint.

11. The allegations in paragraph 11 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Complaint.

12. The allegations in paragraph 12 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Complaint.

13. The allegations in paragraph 13 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 of the Complaint.

14. The allegations in paragraph 14 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Complaint.

15. The allegations in paragraph 15 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint.

16. The allegations in paragraph 16 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint.

17. The allegations in paragraph 17 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint.

18. The allegations in paragraph 18 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint.

19. The allegations in paragraph 19 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Complaint.

20. The allegations in paragraph 20 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 of the Complaint.

21. The allegations in paragraph 21 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint.

22. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint.

23. The allegations in paragraph 23 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint.

24. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 24 of the Complaint.

25. PGM admits only that it packages Prilosec OTC. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the

Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 25 of the Complaint.

26. PGM admits only that it packages Prilosec OTC. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 26 of the Complaint.

27. PGM admits only that it packages Prilosec OTC. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 27 of the Complaint.

28. PGM admits only that it packages Prilosec OTC. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 28 of the Complaint.

29. The allegations in paragraph 29 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint.

30. The allegations in paragraph 30 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Complaint.

31. The allegations in paragraph 31 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 of the Complaint.

32. The allegations in paragraph 32 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32 of the Complaint.

33. The allegations in paragraph 33 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint.

34. The allegations in paragraph 34 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 of the Complaint.

35. The allegations in paragraph 35 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 of the Complaint.

36. The allegations in paragraph 36 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Complaint.

37. The allegations in paragraph 37 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Complaint.

38. The allegations in paragraph 38 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Complaint.

39. The allegations in paragraph 39 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 of the Complaint.

40. The allegations in paragraph 40 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the Complaint.

41. The allegations in paragraph 41 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint.

42. The allegations in paragraph 42 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Complaint.

43. The allegations in paragraph 43 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Complaint.

44. The allegations in paragraph 44 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint.

45. The allegations in paragraph 45 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 of the Complaint.

46. The allegations in paragraph 46 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 of the Complaint.

47. The allegations in paragraph 47 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47 of the Complaint.

48. The allegations in paragraph 48 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Complaint.

49. The allegations in paragraph 49 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 of the Complaint.

50. The allegations in paragraph 50 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 of the Complaint.

51. The allegations in paragraph 51 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the Complaint.

52. The allegations in paragraph 52 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 of the Complaint.

53. The allegations in paragraph 53 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 of the Complaint.

54. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 54 of the Complaint.

55. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 of the Complaint, and therefore denies those allegations.

56. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 of the Complaint, and therefore denies those allegations.

57. The allegations in paragraph 57 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Complaint.

58. The allegations in paragraph 58 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Complaint.

59. The allegations in paragraph 59 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 of the Complaint.

60. The allegations in paragraph 60 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Complaint.

61. The allegations in paragraph 61 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61 of the Complaint.

62. The allegations in paragraph 62 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 of the Complaint.

63. The allegations in paragraph 63 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 of the Complaint.

64. The allegations in paragraph 64 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Complaint.

65. The allegations in paragraph 65 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65 of the Complaint.

66. The allegations in paragraph 66 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 of the Complaint.

67. The allegations in paragraph 67 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 of the Complaint.

68. The allegations in paragraph 68 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68 of the Complaint.

69. The allegations in paragraph 69 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 of the Complaint.

70. The allegations in paragraph 70 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 of the Complaint.

71. The allegations in paragraph 71 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the Complaint.

72. The allegations in paragraph 72 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 72 of the Complaint.

73. The allegations in paragraph 73 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 73 of the Complaint.

74. The allegations in paragraph 74 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 74 of the Complaint.

75. The allegations in paragraph 75 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 75 of the Complaint.

76. The allegations in paragraph 76 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 of the Complaint.

77. The allegations in paragraph 77 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 77 of the Complaint.

78. The allegations in paragraph 78 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the Complaint.

79. The allegations in paragraph 79 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the Complaint.

80. The allegations in paragraph 80 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 of the Complaint.

81. The allegations in paragraph 81 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 of the Complaint.

82. The allegations in paragraph 82 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 of the Complaint.

83. The allegations in paragraph 83 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the Complaint.

84. The allegations in paragraph 84 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84 of the Complaint.

85. The allegations in paragraph 85 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 of the Complaint.

86. The allegations in paragraph 86 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 of the Complaint.

87. The allegations in paragraph 87 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 of the Complaint.

88. The allegations in paragraph 88 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 of the Complaint.

89. The allegations in paragraph 89 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 89 of the Complaint.

90. The allegations in paragraph 90 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 90 of the Complaint.

91. The allegations in paragraph 91 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 91 of the Complaint.

92. PGM admits that The Procter & Gamble Company is an Ohio corporation and has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati.

93. PGM admits that it is an Ohio corporation and has its principal place of business in Ohio, but denies any remaining allegations of paragraph 93 of the Complaint.

94. PGM admits only that it is a wholly-owned subsidiary of P&G. PGM denies the remaining allegations in paragraph 94 of the Complaint.

95. PGM admits only that plaintiff purports to refer to The Procter & Gamble Manufacturing Company and “The Procter & Gamble Company” collectively as “Procter & Gamble Defendants”. PGM denies that plaintiff’s collective reference is proper. PGM denies any remaining allegations in paragraph 95 of the Complaint.

96. The allegations in paragraph 96 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 96 of the Complaint that are directed to it and/or to P&G. PGM denies any remaining allegations in paragraph 96 of the Complaint.

97. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 of the Complaint that are directed to the AstraZeneca defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 97 of the Complaint.

98. PGM admits only that it packages Prilosec OTC. PGM denies the remaining allegations in paragraph 98 of the Complaint.

99. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 99 of the Complaint that are directed to other defendants. PGM denies the remaining allegations in paragraph 99 of the Complaint.

100. PGM denies the allegations in paragraph 100 of the Complaint.

101. PGM admits that FDA approved the NDA for Prilosec OTC, NDA 021229, on or about June 20, 2003. PGM denies the remaining allegations in paragraph 101 of the Complaint.

102. PGM admits only that it packages Prilosec OTC. PGM denies the remaining allegations in paragraph 102 of the Complaint.

103. The allegations in paragraph 103 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 103 of the Complaint.

104. PGM denies the allegations in paragraph 104 of the Complaint.

105. PGM denies the allegations in paragraph 105 of the Complaint.

106. The allegations in paragraph 106 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 of the Complaint.

107. The allegations in paragraph 107 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107 of the Complaint.

108. The allegations in paragraph 108 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Complaint.

109. The allegations in paragraph 109 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Complaint.

110. The allegations in paragraph 110 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the Complaint.

111. The allegations in paragraph 111 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 of the Complaint.

112. The allegations in paragraph 112 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 112 of the Complaint.

113. The allegations in paragraph 113 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 of the Complaint.

114. The allegations in paragraph 114 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 of the Complaint.

115. The allegations in paragraph 115 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without

knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 of the Complaint.

116. The allegations in paragraph 116 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 of the Complaint.

117. The allegations in paragraph 117 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 of the Complaint.

118. The allegations in paragraph 118 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 of the Complaint.

119. The allegations in paragraph 119 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 of the Complaint.

120. The allegations in paragraph 120 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 120 of the Complaint.

121. The allegations in paragraph 121 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 of the Complaint.

122. The allegations in paragraph 122 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122 of the Complaint.

123. The allegations in paragraph 123 of the Complaint are not directed to PGM, and therefore no response is required of PGM. To the extent a response is required, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 of the Complaint.

124. The allegations in paragraph 124 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 124 of the Complaint.

125. The allegations in paragraph 125 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 125 of the Complaint.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. PGM admits only that Prilosec OTC is indicated for frequent heartburn (occurring 2 or more times per week). PGM denies all other allegations in paragraph 126 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 126 of the Complaint, and therefore denies those allegations.

127. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 127 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 127 of the Complaint.

128. PGM denies any allegations in paragraph 128 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128 of the Complaint, and therefore denies those allegations.

129. PGM denies any allegations in paragraph 129 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 129 of the Complaint, and therefore denies those allegations.

130. PGM denies any allegations in paragraph 130 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 130 of the Complaint, and therefore denies those allegations

131. PGM denies any allegations in paragraph 131 of the Complaint that may be directed to it. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 131 of the Complaint, and therefore denies those allegations.

B. PPI Products Cause Severe Kidney Injuries

132. PGM admits only that an article was published in October 1992 in *The American Journal of Medicine*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 132 of the Complaint.

133. PGM denies the allegations in paragraph 133 of the Complaint.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

134. PGM denies the allegations in paragraph 134 of the Complaint.

135. PGM admits only that publications were made in 2006 in *Kidney International*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized those publications. PGM denies the remaining allegations in paragraph 135 of the Complaint.

136. PGM admits only that an article was published in 2007 in “*Alimentary Pharmacology Therapeutics*” titled “Systematic review: proton pump inhibitor-associated acute interstitial nephritis,” involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the name of the publication or the article. PGM denies the remaining allegations in paragraph 136 of the Complaint.

137. PGM admits only that an article was published in February 2007 in the *British Journal of Clinical Pharmacology* titled “Proton pump inhibitor-induced acute interstitial nephritis,” involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 137 of the Complaint.

138. PGM admits only that Public Citizen filed a petition on or about August 23, 2011, with FDA, but denies that plaintiff has completely or accurately characterized the petition. PGM denies the remaining allegations in paragraph 138 of the Complaint.

139. PGM admits only that Public Citizen filed a petition on or about August 23, 2011, with FDA, but denies that plaintiff has completely or accurately characterized the petition. PGM denies the remaining allegations in paragraph 139 of the Complaint.

140. PGM admits only that FDA responded to the August 23, 2011 petition filed by Public Citizen, but denies that plaintiff has completely or accurately characterized FDA's response. PGM denies the remaining allegations in paragraph 140 of the Complaint.

141. PGM admits only that FDA responded to the August 23, 2011 petition filed by Public Citizen, but denies that plaintiff has completely or accurately characterized FDA's response. PGM denies the remaining allegations in paragraph 141 of the Complaint.

142. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Complaint, and therefore denies those allegations.

143. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 143 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 143 of the Complaint are directed to PGM, PGM admits that FDA has concluded over-the-counter PPIs, such as Prilosec OTC, should not contain a warning regarding AIN. PGM denies the remaining allegations in paragraph 143 of the Complaint.

144. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 144 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 144 of the Complaint.

145. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 145 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 145 of the Complaint.

146. PGM denies the allegations in paragraph 146 of the Complaint.

147. PGM denies any allegations in paragraph 147 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 147 of the Complaint, and therefore denies those allegations.

148. PGM denies the allegations in paragraph 148 of the Complaint, including all sub-parts.

149. PGM denies any allegations in paragraph 149 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 149 of the Complaint, and therefore denies those allegations.

150. PGM denies any allegations in paragraph 150 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 150 of the Complaint, and therefore denies those allegations.

151. PGM denies any allegations in paragraph 151 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations in paragraph 151 of the Complaint, and therefore denies those allegations.

ii. PPI-Induced Acute Kidney Injury (“AKI”)

152. PGM denies any allegations in paragraph 152 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM denies the remaining allegations in paragraph 152 of the Complaint.

153. PGM denies the allegations in paragraph 153 of the Complaint.

154. PGM denies the allegations in paragraph 154 of the Complaint.

155. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 155 of the Complaint are directed at PGM, PGM admits that FDA has concluded over-the-counter PPIs, namely Prilosec OTC, should not contain a warning regarding AIN. PGM denies the remaining allegations in paragraph 155 of the Complaint.

156. PGM denies any allegations in paragraph 156 of the Complaint that may be directed to it or that are deemed to imply causation of injury. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 156 of the Complaint, and therefore denies those allegations.

ii. PPI-Induced Chronic Kidney Disease (“CKD”)

157. To the extent the allegations in paragraph 157 of the Complaint are deemed to imply causation of injury, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 157 of the Complaint, and therefore denies those allegations.

158. To the extent the allegations in paragraph 158 of the Complaint are deemed to imply causation of injury, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 158 of the Complaint, and therefore denies those allegations.

159. PGM denies the allegations in paragraph 159 of the Complaint.

160. PGM admits only that an article was published in February 2016 in the *Journal of the American Society of Nephrology*, involving use of certain PPIs, but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 160 of the Complaint.

161. PGM admits only that an article was published in April 2016 in the *Journal of Nephrology*, involving certain kidney conditions, but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 161 of the Complaint.

162. To the extent the allegations in paragraph 162 of the Complaint are deemed to imply causation of injury, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 162 of the Complaint, and therefore denies those allegations.

163. PGM admits Xie, Yan, et al., published an article “Long-term kidney outcomes among users of proton pump inhibitors without intervening acute kidney injury,” but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 163 of the Complaint.

164. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 164 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 164 of the Complaint.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. To the extent the allegations in paragraph 165 of the Complaint are directed to PGM or are deemed to imply causation of injury, they are denied. PGM denies the remaining allegations in paragraph 165 of the Complaint.

166. To the extent the allegations in paragraph 166 of the Complaint are directed to PGM or are deemed to imply causation of injury, they are denied. PGM denies the remaining allegations in paragraph 166 of the Complaint.

167. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 167 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 167 of the Complaint.

168. To the extent the allegations in paragraph 168 of the Complaint are directed to PGM or are deemed to imply causation of injury, they are denied. PGM denies the remaining allegations in paragraph 168 of the Complaint.

169. PGM denies the allegations in paragraph 169 of the Complaint.

170. PGM denies the allegations in paragraph 170 of the Complaint.

171. To the extent the allegations in paragraph 171 of the Complaint are directed to PGM or are deemed to imply causation of injury, they are denied. PGM denies the remaining allegations in paragraph 171 of the Complaint.

172. PGM denies the allegations in paragraph 172 of the Complaint.

173. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 of the Complaint that are directed to other defendants or products, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 173 of the Complaint.

D. Safer Alternatives to PPIs

174. To the extent the allegations in paragraph 174 of the Complaint are deemed to imply causation of damages, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 174 of the Complaint.

175. PGM admits D. Marks published an article “Time to halt the overprescribing of proton pump inhibitor therapy,” but denies that plaintiff has completely or accurately characterized the article. PGM denies the remaining allegations in paragraph 175 of the Complaint

176. To the extent the allegations in paragraph 176 of the Complaint are deemed to imply causation of damages, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 176 of the Complaint.

E. Injuries Resulting from PPI Products

177. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 177 of the Complaint.

178. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 178 of the Complaint.

179. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 179 of the Complaint.

180. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 180 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 180 of the Complaint.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

181. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 181 of the Complaint.

182. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 182 of the Complaint.

183. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 183 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 183 of the Complaint.

184. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 184 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 184 of the Complaint.

185. The allegations in paragraph 185 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 185 of the Complaint, and therefore denies those allegations.

186. The allegations in paragraph 186 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 186 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 186 of the Complaint.

187. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 187 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 187 of the Complaint.

188. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 188 the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 188 of the Complaint.

189. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 189 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 189 of the Complaint.

190. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 190 of the Complaint.

191. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 191 of the Complaint.

192. To the extent the allegations in paragraph 192 of the Complaint are deemed to imply causation of injury or damages, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192 of the Complaint that are directed to other defendants, and therefore denies those allegations. To the extent the allegations in paragraph 192 of the Complaint are directed at PGM, PGM states that FDA has concluded over-the-counter PPIs, namely Prilosec OTC, should not contain a warning regarding AIN. PGM denies the remaining allegations in paragraph 192 of the Complaint.

193. To the extent the allegations in paragraph 193 of the Complaint are deemed to imply causation of damages or injury, they are denied. PGM is without knowledge or information

sufficient to form a belief as to the truth of the allegations in paragraph 193 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 193 of the Complaint.

194. To the extent the allegations in paragraph 194 of the Complaint are deemed to imply causation of damages or injury, they are denied. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 194 of the Complaint.

195. The allegations in paragraph 195 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 195 of the Complaint.

G. Defendants Violation of Federal Law

196. The allegations in paragraph 196 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 196 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 196 of the Complaint.

197. The allegations in paragraph 197 of the Complaint, including all sub-parts, are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a

belief as to the truth of the allegations in paragraph 197 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 197 of the Complaint, including all sub-parts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. PGM incorporates its responses to paragraphs 1 through 197 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 198 of the Complaint.

199. The allegations in paragraph 199 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 199 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 199 of the Complaint.

200. The allegations in paragraph 200 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 200 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 200 of the Complaint.

201. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 201 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 201 of the Complaint.

202. The allegations in paragraph 202 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 202 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 202 of the Complaint.

203. The allegations in paragraph 203 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 203 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 203 of the Complaint.

204. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 204 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 204 of the Complaint.

205. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 205 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 205 of the Complaint.

206. PGM denies the allegations in paragraph 206 of the Complaint.

207. PGM is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in paragraph 207 of the Complaint about what plaintiff's doctors

allegedly said to plaintiff, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 207 of the Complaint.

208. PGM denies the allegations in paragraph 208 of the Complaint.

209. To the extent the allegations in paragraph 209 of the Complaint are allegations of conclusions of law, no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 209 of the Complaint.

210. To the extent the allegations in paragraph 210 of the Complaint are allegations of conclusions of law, no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 210 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 210 of the Complaint.

211. PGM is without knowledge or information sufficient at this time to form a belief as to the truth of the allegations in paragraph 211 of the Complaint about conversations plaintiff may have had with their doctors, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 211 of the Complaint.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

212. PGM incorporates its responses to paragraphs 1 through 211 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 212 of the Complaint.

213. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 213 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 213 of the Complaint.

214. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 214 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 214 of the Complaint.

215. PGM admits only that it distributes Prilosec OTC, but PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215 of the Complaint about what products the plaintiff used, and therefore denies those allegations. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 215 of the Complaint.

216. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 216 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 216 of the Complaint.

217. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 217 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 217 of the Complaint.

218. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 218 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 218 of the Complaint.

219. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 219 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 219 of the Complaint.

220. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 220 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 220 of the Complaint.

221. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 221 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 221 of the Complaint.

222. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 222 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 222 of the Complaint.

223. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 223 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 223 of the Complaint.

224. The allegations in paragraph 224 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of

the allegations in paragraph 224 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 224 of the Complaint.

225. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 225 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 225 of the Complaint.

226. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 226 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 226 of the Complaint.

227. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 227 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 227 of the Complaint.

228. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 228 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 228 of the Complaint.

229. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 229 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 229 of the Complaint.

230. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 230 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 230 of the Complaint.

231. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 231 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 231 of the Complaint.

232. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 232 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 232 of the Complaint.

233. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 233 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 233 of the Complaint.

234. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 234 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 234 of the Complaint.

235. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 235 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 235 of the Complaint.

236. PGM denies the allegations in paragraph 236 of the Complaint.

237. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 237 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 237 of the Complaint, including all sub-parts.

238. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 238 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 238 of the Complaint.

239. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 239 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 239 of the Complaint.

240. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 240 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 240 of the Complaint.

241. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 241 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 241 of the Complaint.

242. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 242 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 242 of the Complaint.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

243. PGM incorporates its responses to paragraphs 1 through 242 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 243 of the Complaint.

244. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 244 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 244 of the Complaint.

245. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 245 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 245 of the Complaint.

246. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 246 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 246 of the Complaint.

247. PGM denies the allegations in paragraph 247 of the Complaint.

248. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 248 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 248 of the Complaint.

249. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 249 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 249 of the Complaint.

250. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 250 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 250 of the Complaint.

251. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 251 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 251 of the Complaint.

252. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 252 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 252 of the Complaint.

253. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 253 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 253 of the Complaint.

254. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 254 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 254 of the Complaint.

255. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 255 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 255 of the Complaint.

256. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 256 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 256 of the Complaint.

257. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 257 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 257 of the Complaint, including all sub-parts.

258. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 258 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 258 of the Complaint.

259. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 259 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 259 of the Complaint.

260. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 260 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 260 of the Complaint.

261. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 261 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 261 of the Complaint.

262. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 262 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 262 of the Complaint.

263. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 263 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 263 of the Complaint.

264. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 264 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 264 of the Complaint.

265. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 265 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 265 of the Complaint.

266. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 266 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 266 of the Complaint.

267. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 267 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 267 of the Complaint.

268. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 268 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 268 of the Complaint.

269. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 269 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 269 of the Complaint.

270. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 270 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 270 of the Complaint.

271. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 271 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 271 of the Complaint.

272. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 272 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 272 of the Complaint.

273. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 273 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 273 of the Complaint.

274. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 274 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 274 of the Complaint.

275. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 275 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 275 of the Complaint.

276. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 276 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 276 of the Complaint.

277. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 277 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 277 of the Complaint.

278. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 278 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 278 of the Complaint.

279. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 279 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 279 of the Complaint.

280. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 280 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 280 of the Complaint.

281. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 281 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 281 of the Complaint.

282. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 282 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 282 of the Complaint.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. PGM incorporates its responses to paragraphs 1 through 282 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 283 of the Complaint.

284. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 284 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 284 of the Complaint.

285. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 285 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 285 of the Complaint.

286. The allegations in paragraph 286 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 286 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 286 of the Complaint.

287. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 287 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 287 of the Complaint.

288. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 288 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 288 of the Complaint.

289. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 289 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 289 of the Complaint.

290. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 290 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 290 of the Complaint.

291. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 291 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 291 of the Complaint.

292. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 292 of the Complaint that are directed to other defendants,

and therefore denies those allegations. PGM denies the remaining allegations in paragraph 292 of the Complaint.

293. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 293 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 293 of the Complaint.

294. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 294 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 294 of the Complaint.

295. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 295 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 295 of the Complaint.

296. The allegations in paragraph 296 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 296 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 296 of the Complaint.

297. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 297 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 297 of the Complaint.

298. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 298 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 298 of the Complaint.

299. The allegations in paragraph 299 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 299 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 299 of the Complaint.

300. PGM without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 300 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 300 of the Complaint.

301. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 301 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 301 of the Complaint.

302. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 302 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 302 of the Complaint.

303. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 303 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 303 of the Complaint.

304. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 304 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 304 of the Complaint.

305. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 305 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 305 of the Complaint.

306. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 306 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 306 of the Complaint.

307. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 307 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 307 of the Complaint.

308. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 308 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 308 of the Complaint.

309. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 309 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 309 of the Complaint.

310. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 310 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 310 of the Complaint.

311. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 311 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 311 of the Complaint.

312. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 312 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 312 of the Complaint.

COUNT IV
NEGLIGENCE

313. PGM incorporates its responses to paragraphs 1 through 312 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 313 of the Complaint.

314. The allegations in paragraph 314 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 314 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 314 of the Complaint.

315. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 315 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 315 of the Complaint.

316. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 316 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 316 of the Complaint, including all sub-parts.

317. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 317 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 317 of the Complaint.

318. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 318 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 318 of the Complaint.

319. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 319 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 319 of the Complaint.

320. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 320 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 320 of the Complaint.

321. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 321 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 321 of the Complaint.

322. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 322 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 322 of the Complaint.

323. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 323 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 323 of the Complaint.

324. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 324 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 324 of the Complaint.

325. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 325 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 325 of the Complaint.

326. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 326 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 326 of the Complaint.

COUNT V
NEGLIGENCE PER SE

327. PGM incorporates its responses to paragraphs 1 through 326 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 327 of the Complaint.

328. The allegations in paragraph 328 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 328 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 328 of the Complaint.

329. The allegations in paragraph 329 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 329 of the Complaint.

330. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 330 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 330 of the Complaint.

331. The allegations in paragraph 331 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 331 of the Complaint.

332. The allegations in paragraph 332 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM denies the allegations in paragraph 332 of the Complaint.

333. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 333 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 333 of the Complaint.

334. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 334 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 334 of the Complaint.

COUNT VI
NEGLIGENCE—FAILURE TO TEST

335. PGM incorporates its responses to paragraphs 1 through 334 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 335 of the Complaint.

336. The allegations in paragraph 336 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or

necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 336 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 336 of the Complaint.

337. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 337 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 337 of the Complaint.

338. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 338 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 338 of the Complaint.

339. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 339 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 339 of the Complaint.

340. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 340 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 340 of the Complaint.

341. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 341 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 341 of the Complaint.

342. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 342 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 342 of the Complaint.

343. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 343 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 343 of the Complaint.

344. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 344 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 344 of the Complaint.

345. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 345 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 345 of the Complaint.

346. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 346 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 346 of the Complaint.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NONCONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

347. PGM incorporates its responses to paragraphs 1 through 346 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 347 of the Complaint.

348. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 348 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 348 of the Complaint.

349. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 349 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 349 of the Complaint.

350. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 350 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 350 of the Complaint.

351. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 351 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 351 of the Complaint.

352. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 352 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 352 of the Complaint.

353. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 353 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 353 of the Complaint.

354. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 354 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 354 of the Complaint.

355. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 355 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 355 of the Complaint.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. PGM incorporates its responses to paragraphs 1 through 355 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 356 of the Complaint.

357. The allegations in paragraph 357 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 357 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 357 of the Complaint.

358. The allegations in paragraph 358 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or

necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 358 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 358 of the Complaint.

359. The allegations in paragraph 359 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 359 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 359 of the Complaint.

360. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 360 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 360 of the Complaint.

361. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 361 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 361 of the Complaint.

362. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 362 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 362 of the Complaint.

363. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 363 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 363 of the Complaint.

364. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 364 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 364 of the Complaint, including all sub-parts.

365. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 365 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 365 of the Complaint.

366. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 366 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 366 of the Complaint.

367. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 367 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 367 of the Complaint.

368. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 368 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 368 of the Complaint.

369. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 369 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 369 of the Complaint.

370. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 370 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 370 of the Complaint.

371. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 371 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 371 of the Complaint.

372. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 372 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 372 of the Complaint.

373. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 373 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 373 of the Complaint.

374. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 374 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 374 of the Complaint.

375. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 375 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 375 of the Complaint.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. PGM incorporates its responses to paragraphs 1 through 375 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 376 of the Complaint.

377. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 377 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 377 of the Complaint.

378. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 378 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 378 of the Complaint.

379. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 379 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 379 of the Complaint.

380. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 380 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 380 of the Complaint.

381. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 381 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 381 of the Complaint.

382. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 382 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 382 of the Complaint.

383. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 383 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 383 of the Complaint.

384. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 384 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 384 of the Complaint.

385. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 385 of the Complaint with respect to plaintiff's "skills" or

allegations that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 385 of the Complaint.

386. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 386 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 386 of the Complaint.

387. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 387 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 387 of the Complaint.

388. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 388 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 388 of the Complaint.

389. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 389 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 389 of the Complaint.

COUNT X
NEGLIGENT MISREPRESENTATION

390. PGM incorporates its responses to paragraphs 1 through 389 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 390 of the Complaint.

391. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 391 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 391 of the Complaint.

392. The allegations in paragraph 392 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 392 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 392 of the Complaint.

393. The allegations in paragraph 393 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 393 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 393 of the Complaint.

394. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 394 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 394 of the Complaint.

395. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 395 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 395 of the Complaint.

396. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 396 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 396 of the Complaint.

397. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 397 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 397 of the Complaint.

398. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 398 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 398 of the Complaint.

399. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 399 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 399 of the Complaint.

400. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 400 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 400 of the Complaint.

COUNT IX
FRAUD AND FRAUDULENT MISREPRESENTATION

401. PGM incorporates its responses to paragraphs 1 through 400 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 401 of the Complaint.

402. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 402 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 402 of the Complaint.

403. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 403 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 403 of the Complaint.

404. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 404 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 404 of the Complaint.

405. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 405 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 405 of the Complaint.

406. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 406 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 406 of the Complaint.

407. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 407 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 407 of the Complaint.

408. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 408 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 408 of the Complaint.

409. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 409 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 409 of the Complaint.

410. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 410 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 410 of the Complaint.

411. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 411 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 411 of the Complaint.

412. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 412 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 412 of the Complaint.

413. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 413 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 413 of the Complaint.

COUNT XII
GROSS NEGLIGENCE

414. PGM incorporates its responses to paragraphs 1 through 413 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 414 of the Complaint.

415. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 415 of the Complaint, including all sub-parts, that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 415 of the Complaint, including all sub-parts.

416. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 416 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 416 of the Complaint.

COUNT XIII
FRAUDULENT CONCEALMENT

417. PGM incorporates its responses to paragraphs 1 through 416 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 417 of the Complaint.

418. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 418 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 418 of the Complaint.

419. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 419 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 419 of the Complaint.

420. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 420 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 420 of the Complaint.

421. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 421 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 421 of the Complaint.

422. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 422 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 422 of the Complaint.

423. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 423 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 423 of the Complaint.

424. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 424 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 424 of the Complaint.

425. The allegations in paragraph 425 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 425 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 425 of the Complaint.

426. The allegations in paragraph 426 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 426 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 426 of the Complaint.

427. The allegations in paragraph 427 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 427 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 427 of the Complaint.

428. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 428 of the Complaint that are directed to other defendants, and

therefore denies those allegations. PGM denies the remaining allegations in paragraph 428 of the Complaint.

429. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 429 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 429 of the Complaint.

430. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 430 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 430 of the Complaint.

431. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 431 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 431 of the Complaint.

432. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 432 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM specifically denies making any knowingly and intentionally false and misleading statements regarding Prilosec OTC and denies the remaining allegations in paragraph 432 of the Complaint.

433. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 433 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies having maliciously or intentionally concealed

material information from plaintiff and/or plaintiff's healthcare providers regarding Prilosec OTC and further denies the remaining allegations in paragraph 433 of the Complaint.

434. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 434 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 434 of the Complaint.

435. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 435 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 435 of the Complaint.

436. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 436 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 436 of the Complaint.

437. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 437 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 437 of the Complaint.

438. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 438 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies that it concealed any hazards associated with Prilosec OTC use and further denies the remaining allegations in paragraph 438 of the Complaint.

439. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 439 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 439 of the Complaint.

440. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 440 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 440 of the Complaint.

441. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 441 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 441 of the Complaint.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. PGM incorporates its responses to paragraphs 1 through 441 above as if fully set forth herein. PGM denies the remaining allegations in paragraph 442 of the Complaint.

443. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 443 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 443 of the Complaint.

444. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 444 of the Complaint, including all sub-parts, that are directed to

other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 444 of the Complaint, including all sub-parts.

445. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 445 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 445 of the Complaint.

446. PGM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 446 of the Complaint that are directed to other defendants, and therefore denies those allegations. PGM denies the remaining allegations in paragraph 446 of the Complaint.

447. To the extent demands or statements in the “Wherefore” paragraphs of the Complaint are directed to PGM or are deemed to be allegations or other statements that PGM is liable to plaintiff, they are denied, and PGM specifically denies that plaintiff is entitled to any relief whatsoever.

448. PGM denies any and all allegations or other statements contained in headings and captions of the Complaint.

449. PGM denies any and all allegations or statements in the Complaint except those that PGM has expressly admitted in its answer to this Complaint.

DEFENSES

By asserting these defenses, PGM does not admit that it has the burden of proof or persuasion with respect to any of these defenses. Subject to further investigation and without waiving any additional defenses, PGM asserts the following defenses:

1. Plaintiff’s Complaint fails to state a claim upon which relief can be granted.

2. Plaintiff's Complaint should be dismissed and/or transferred for lack of venue and/or on the grounds of *forum non conveniens*.

3. PGM asserts any and all defenses of lack of personal jurisdiction that are now or may become applicable in any plaintiff's case.

4. Plaintiff's claims may be barred because of plaintiff's failure to join necessary and indispensable parties.

5. Plaintiff's claims may be barred, in whole or in part, by the doctrines of release, estoppel, accord and satisfaction, unclean hands, res judicata, laches, and/or waiver.

6. Plaintiff's claims are barred, in whole or in part, because plaintiff lacks standing or capacity to bring such claims and/or is not the real party in interest.

7. Plaintiff's claims are barred, in whole or in part, because Prilosec OTC is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and plaintiff's claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with determinations by the FDA specifying the language that should be used in the labeling accompanying Prilosec OTC. Accordingly, plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

8. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and PGM hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

9. PGM hereby pleads all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22 – 2307.29.

10. PGM asserts and incorporates all defenses, offsets, and remedies for contribution under Ohio Rev. Code §§ 2307.25 – 2307.26.

11. Plaintiff's claims are barred because Prilosec OTC is an "ethical drug" as defined by Ohio Rev. Code Ann. § 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of Prilosec OTC.

12. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory principles set forth in Ohio Rev. Code Ann. §§ 2315.32– 2315.36.

13. Plaintiff's recovery as against PGM should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.

14. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.

15. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

16. Plaintiff's Complaint fails to state a claim for unlawful conduct or for false or misleading business practices under Ohio Rev. Code Ann. §§ 1345.01, *et seq.*

17. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

18. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

19. Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. §1345.12(C), specifically precludes claims for personal injury.

20. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Rev. Code Ann. § 2307.711.

21. All or part of the injuries or damages alleged in plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct PGM had no reason to anticipate and for whose conduct PGM is not and were not responsible. Ohio Rev. Code Ann. § 2307.22, *et seq.*

22. The injuries or damages of which plaintiff complains were caused or contributed to by one or more persons from whom the plaintiff do not seek recovery in this action. Ohio Rev. Code Ann. § 2307.23.

23. One or more of plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Rev. Code Ann. §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, *et al.*

24. Plaintiff's claims are barred, in whole or in part, because PGM exercised reasonable care, acted in good faith, and gave adequate warnings of all known or reasonably knowable risks associated with the use of Prilosec OTC at all relevant times. *See* Ohio Rev. Code Ann. § 2307.76(A) & (B).

25. Plaintiff's claims are barred by the learned intermediary doctrine, as codified by Ohio Rev. Code Ann. § 2307.76(C).

26. Plaintiff's design defect claims fail under Ohio Rev. Code Ann. § 2307.75(D) because adequate warning and instruction were provided under Ohio Rev. Code Ann. § 2307.76 concerning any unavoidably unsafe aspects of the product.

27. Plaintiff's design defect claims fail under Ohio Rev. Code Ann. § 2307.75(E) because the alleged risk of which plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

28. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Rev. Code Ann. § 2307.75(F).

29. Prilosec OTC complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of these products, and that they were neither defective nor unreasonably dangerous.

30. PGM, at all times, used reasonable care, skill, and diligence, and complied with generally accepted standards in the industry.

31. Prilosec OTC complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States or by applicable state law, or by any agency of the United States or applicable state.

32. Plaintiff's inadequate warning claims are barred under Ohio Rev. Code Ann. § 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

33. Plaintiff's claims for punitive or exemplary damages as set forth in the Complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).

34. To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and its progeny.

35. Plaintiff's fraud-based claims may be barred, in whole or in part, because plaintiff did not rely to their detriment upon any statement by PGM in deciding to use Prilosec OTC.

36. PGM is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any applicable law, rule of law, or governing statute of any state, including but not limited to any relevant product liability acts and/or consumer fraud and/or unfair competition acts, that would bar or otherwise limit any of the claims asserted by plaintiff.

37. Plaintiff's claims may be barred by the doctrine(s) contained in Restatement (Second) of Torts § 402A, and comments thereto, including but not limited to comments j and k, and/or Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

38. The benefits and utility of Prilosec OTC outweigh the risk of danger or harm, if any, inherent in the product.

39. Plaintiff's claims may be barred, in whole or in part, by misuse or unintended use of Prilosec OTC.

40. Plaintiff's claims may be barred because plaintiff's injuries, if any, were caused, in whole or in part, by the intervening or superseding conduct of plaintiff, independent third parties,

or events that were extraordinary under the circumstances, not foreseeable in the normal course, or independent of or far removed from PGM's conduct or control.

41. Plaintiff's claims may be barred, in whole or in part, because plaintiff provided learned or informed consent to the use of Prilosec OTC.

42. Plaintiff's claims may be barred, in whole or in part, by the negligent and/or otherwise wrongful conduct of others, constituting an intervening or superseding cause of the alleged harm.

43. Plaintiff's claims may be barred, in whole or in part, by applicable statutes of limitations and/or repose.

44. Plaintiff's claims may be barred by prescription.

45. To the extent plaintiff assert claims for breach of express or implied warranty, plaintiff lack the requisite privity with PGM to maintain such claims.

46. To the extent plaintiff assert claims for breach of express or implied warranty, such claims are barred because plaintiff did not reasonably rely upon any alleged express or implied warranty, and because plaintiff did not give PGM adequate notice of any alleged breach of warranty, express or implied.

47. Plaintiff's have no right to assert a claim that PGM's product is unreasonably dangerous because of nonconformity to an express warranty because plaintiff can neither prove the existence of such an explicit warranty nor any causal relationship between an express warranty, if one was communicated to plaintiff, and plaintiff's alleged damage.

48. To the extent that plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

49. To the extent plaintiff seek recovery of punitive or exemplary damages against PGM, any such damages are barred and/or limited by applicable laws and/or standards of proof.

50. Plaintiff's claims for punitive damages cannot be sustained because an award of punitive damages by a jury that is not specifically instructed on the size, guidelines, or limits of punitive damages imposed and provided a sufficient clarity for determining such an award, not subject to judicial review on the basis of an objective standard, is arbitrary and capricious, and would violate due process and the equal protection rights guaranteed by the Fourteenth Amendment of the United States Constitution and the double jeopardy clause of the Fifth Amendment and corresponding provisions of the Constitution of any state whose law is deemed to apply in this case.

51. Plaintiff's claims for punitive damages are barred and are in violation of the due process of law clause of the Fifth and Fourteenth Amendments to the United States Constitution, and are in violation of the prohibition of *ex post facto* laws contained in Section 10, Paragraph 1 of Article 1 of the United States Constitution.

52. Any civil penalties and remedies sought by plaintiff are unconstitutional and barred as excessive fines or penalties prohibited under the Eighth and Fourteenth Amendments to the United States Constitution.

53. To the extent plaintiff seek recovery of punitive, exemplary or aggravated damages against PGM, any such claims are in violation of and are barred by the Constitution of the United States and any relevant comparable state constitutional provisions, including but not limited to, the Due-Process and Equal Protection Clauses contained in the Fifth and Fourteenth Amendments; the Excessive Fines Clause of the Eighth Amendment; and the Tenth Amendment.

54. To the extent that plaintiff seeks punitive, exemplary, or aggravated damages, PGM specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and cases subsequent to *BMW*, including *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007).

55. Punitive damages, if any, must be apportioned among all potentially responsible parties and nonparties. The true identity of all such potentially responsible nonparties is not presently known to PGM. PGM reserves the right to supplement.

56. Plaintiff's claims are barred to the extent the injuries alleged in the Complaint, and/or any applicable individual complaint, were idiopathic in nature or caused or enhanced by preexisting or unrelated medical, genetic, environmental, or psychiatric conditions, diseases, or illnesses, by plaintiff's own idiosyncratic reactions to the product(s), and/or by operation of nature.

57. If plaintiff sustained the injuries or damages alleged, they were caused, in whole or in part, by operation of nature or by act of God.

58. Plaintiff's damages, if any, may be limited, in whole or in part, by plaintiff's failure to mitigate.

59. Plaintiff's claim that PGM product was unreasonably dangerous because of an inadequate warning fails because PGM owed plaintiff no warning at all given that plaintiff already knew or reasonably should have been expected to know of the characteristic of the product that could cause damage and the danger thereof.

60. Any injuries or damages sustained by plaintiff were directly and proximately caused by failure of plaintiff to heed warnings and instructions.

61. Plaintiff's claims are barred because there is no evidence that plaintiff's health care providers would have heeded any different warnings than those provided.

62. At all times, Prilosec OTC was distributed and/or sold in compliance with all applicable federal, state and local laws and regulations, and rules promulgated and enforced by the FDA.

63. Prilosec OTC is and was formulated, tested, manufactured, distributed, and labeled in accordance with the provisions of the federal Food Drug and Cosmetic Act and the regulations promulgated pursuant thereto.

64. Any communications and/or actions between any defendant and the FDA and/or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

65. Plaintiff's claims are barred, in whole or in part, because commercial speech relating to the subject product is protected under the First Amendment of the United States Constitution and the applicable state constitution.

66. At the time the alleged product would have left this defendant's control, it did not know, and, in light of then-existing reasonably available scientific and technical knowledge, it could not have known of the characteristic that allegedly caused the damage alleged in the Complaint, and/or applicable individual complaint, or the danger of such characteristic. To the contrary, reasonably available scientific and technical knowledge indicates that if the alleged product of this defendant is used as directed, there is no appreciable possibility that the product will cause the damage herein alleged.

67. The product allegedly involved in this action was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused, or contributed to, plaintiff's alleged damages, if any.

68. PGM had no duty to warn about any possible dangers that were not known at the time of manufacture and sale of the product in question.

69. Prilosec OTC, when properly used, is and was safe and fit for its intended use and purpose at all relevant times.

70. PGM's actions, if any, and Prilosec OTC conformed to the state of the art and the trade and custom in the industry as they existed at the time.

71. Plaintiff are barred, in whole or in part, from recovery due to spoliation of evidence.

72. To the extent that any medical or hospital expenses claimed by plaintiff have been, or will be, indemnified in whole or in part, from any collateral source, any verdict or judgment against defendant must be reduced by those amounts pursuant to applicable state law.

73. To the extent that any or all of plaintiff's claims have been settled, compromised, or otherwise discharged, a set-off is due. PGM avails itself of each and every set-off or defense available under applicable state law.

74. The claims against PGM, separately and severally, are barred by the Commerce Clause of the United States Constitution because they would, if allowed, impose an undue burden on interstate commerce.

75. PGM adopts and relies upon all provisions and defenses afforded it under the United States Constitution and any applicable state constitution(s).

76. PGM claims the benefits of any disclaimers and/or limitations on its liability made to anyone involved in the manufacture, distribution, or sale of Prilosec OTC.

77. To the extent applicable, PGM asserts and preserves all claims for indemnification and/or contribution from any person and/or entity whose negligence or other fault contributed to plaintiff's alleged injuries and damages.

78. Plaintiff's claims may be barred because plaintiff has failed to comply with conditions precedent necessary to bring this action and/or each particular cause of action asserted by plaintiff.

79. Plaintiff's claims are barred, in whole or in part, by the laws of other jurisdictions.

80. To the extent plaintiff has attempted to plead any common law claims, such claims are preempted, superseded, and/or subsumed by applicable state law.

81. With respect to each and every purported cause of action, the acts of PGM, if any, were at all times done in good faith and without malice.

82. PGM incorporates all defenses available to it under any applicable law.

83. PGM incorporates the defenses of all others who are or may become parties to this action as if fully set forth herein.

84. PGM reserves the right to amend its answer to add additional defenses and/or averments as additional information becomes available.

WHEREFORE, PREMISES CONSIDERED, The Procter & Gamble Manufacturing Company, respectfully prays for the following relief:

1. That judgment be entered in its favor, dismissing the Complaint, and/or any applicable individual complaint, in its entirety with prejudice.

2. That judgment be entered in its favor for costs incurred in connection with this matter; and

3. That this Court grant it such other and further relief, both at law and in equity, whether general or special, to which it may be justly entitled.

JURY DEMAND

Now comes The Procter & Gamble Manufacturing Company, and files this JURY DEMAND and requests a trial by jury in each and every case.

Respectfully Submitted,

/s/ Emily S. Prem

Emily S. Prem (0093988)

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***Counsel for Defendant The Procter & Gamble
Manufacturing Company***

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing document was served this 23rd day of July, 2019 by United States First Class Mail, postage prepaid, upon the following:

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/s/ Emily S. Prem

PROOF OF SERVICE

I hereby certify that on July 31, 2019, foregoing **Notice of Appearance** was filed electronically and that a copy has been served upon counsel of record by the court's electronic filing system.

/s/ Tariq M. Naeem

Tariq M. Naeem (0072808)

*Attorney for Defendants Abbott Laboratories,
Takeda Pharmaceuticals U.S.A., Inc., Takeda
Pharmaceuticals America, Inc., Takeda
Development Center Americas, Inc., and Takeda
Pharmaceutical Company Limited*

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A BEHYMER,

Plaintiff,

v.

ABBOTT LABORATORIES, et al.,

Defendants.

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Civil Action No.: A1902638

JURY DEMAND ENDORSED
HEREON

**ANSWER AND DEFENSES OF ASTRAZENECA PHARMACEUTICALS LP AND
ASTRAZENECA LP TO PLAINTIFF’S COMPLAINT AND JURY DEMAND**

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (“AstraZeneca”)¹, by counsel, hereby answers and responds to Plaintiff’s Complaint and Jury Demand (“Complaint”). AstraZeneca responds herein to the allegations in the Complaint insofar as such allegations pertain to AstraZeneca. Except as otherwise expressly set forth below, AstraZeneca denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations refer or relate to any other defendant, person or entity. Any allegations, averments, contentions or statements in the Complaint not specifically and unequivocally admitted in this Answer are denied. AstraZeneca responds to each of the paragraphs of the Complaint as follows:

¹ Defendant AstraZeneca LP dissolved as a legal entity on December 31, 2018.



NATURE OF THE ACTION²

1. AstraZeneca admits that Plaintiff has attempted to assert a cause of action for personal injuries, but denies that Plaintiff is entitled to the relief sought. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint based on Plaintiff's personal knowledge and belief, and therefore denies those allegations. AstraZeneca denies all remaining allegations in Paragraph 1 of the Complaint.

2. Because there are no legal or factual allegations contained in Paragraph 2, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations of Paragraph 2.

3. AstraZeneca denies the allegations of Paragraph 3.

4. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States and that Plaintiff has attempted to assert a cause of action for personal injuries, but denies the remaining allegations set forth in Paragraph 4.

5. AstraZeneca admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 5.

PARTIES, JURISDICTION & VENUE

6. The allegations in Paragraph 6 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, AstraZeneca admits only that Plaintiff alleges in this Complaint that the amount in controversy alleged exceeds the sum of \$25,000 exclusive of interest and costs. AstraZeneca is

² AstraZeneca has utilized the headings contained in Plaintiff's Complaint. To the extent Plaintiff's headings set forth legal or factual allegations that require AstraZeneca to respond, AstraZeneca denies the allegations set forth therein.

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6 of the Complaint, and therefore denies those allegations.

I. PLAINTIFF

7. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint, including all sub-parts, regarding Plaintiff's residency, Plaintiff's alleged use of PPIs, and the conditions Plaintiff allegedly was diagnosed with, and therefore denies those allegations. AstraZeneca denies all remaining allegations in Paragraph 7.

II. DEFENDANTS

8. The allegations set forth in Paragraph 8 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 8, and, therefore, denies same.

9. The allegations set forth in Paragraph 9 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 9, and, therefore, denies same.

10. The allegations set forth in Paragraph 10 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10, and, therefore, denies same.

11. The allegations set forth in Paragraph 11 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 11 and, therefore, denies same.

12. The allegations set forth in Paragraph 12 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12, and, therefore, denies same.

13. The allegations set forth in Paragraph 13 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 13, and, therefore, denies same.

14. AstraZeneca admits the allegations set forth in Paragraph 14.

15. AstraZeneca admits that AstraZeneca LP was a limited partnership organized under the laws of Delaware with its principal place of business in Delaware, and that AstraZeneca PLC was the ultimate parent company of AstraZeneca LP, but denies the remaining allegations set forth in Paragraph 15 as stated. Answering further, AstraZeneca states that AstraZeneca LP was dissolved on December 31, 2018.

16. Because there are no legal or factual allegations contained in Paragraph 16, no response is required.

17. To the extent Paragraph 17 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that the general partnership of AstraZeneca Pharmaceuticals LP and AstraZeneca LP speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 17.

18. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 18 as stated.

19. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 19 as stated.

20. To the extent Paragraph 20 states legal conclusions, or contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that in 1982, certain AstraZeneca Defendants (and/or their predecessors) entered into agreements with Merck & Co., Inc. (now Merck Sharp & Dohme Corp.), and the agreements speak for themselves. AstraZeneca denies the remaining allegations set forth in Paragraph 20.

21. AstraZeneca denies the allegations set forth in Paragraph 21 but states that subsequent to entry into the agreements referenced in its response to Paragraph 21, certain AstraZeneca Defendants (and/or their predecessors) and/or Merck & Co., Inc. (now Merck Sharp & Dohme Corp.) developed omeprazole, later known as brand name Prilosec.

22. AstraZeneca admits that Prilosec® is an FDA-approved prescription medication and the conditions for which it is indicated are set forth in the product label. AstraZeneca denies the remaining allegations set forth in Paragraph 22 as stated.

23. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 23 as stated.

24. To the extent the Paragraph 24 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca

states that the agreement referenced in Paragraph 24 speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 24 as stated.

25. To the extent the Paragraph 25 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 25 speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 25 as stated.

26. To the extent the Paragraph 26 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 26 speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 26 as stated.

27. To the extent the Paragraph 27 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 27 speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 27 as stated.

28. To the extent the Paragraph 28 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 28 speaks for itself. AstraZeneca denies the remaining allegations set forth in Paragraph 28 as stated.

29. AstraZeneca admits that Prilosec® is an FDA-approved medication and that the conditions for which it is indicated are set forth in the product label. AstraZeneca denies the remaining allegations set forth in Paragraph 29 as stated.

30. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® in the United States. AstraZeneca denies the allegations set forth in Paragraph 30 as stated.

31. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® in the United States. AstraZeneca denies the allegations set forth in Paragraph 31 as stated.

32. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 32 as stated.

33. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® and Nexium® in the United States and that AstraZeneca entities developed Nexium®. AstraZeneca denies the remaining allegations set forth in Paragraph 33 as stated.

34. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 34 as stated.

35. AstraZeneca admits that Nexium® is an FDA-approved medication and that the conditions for which it is indicated are set forth in the product label. AstraZeneca denies the remaining allegations set forth in Paragraph 35 as stated.

36. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 36 as stated.

37. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 37 as stated.

38. AstraZeneca is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 38, including the undefined, subjective term “largest amount spent,” and, therefore, denies the same.

39. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® and Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 39 as stated.

40. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® and Nexium® in the United States. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 40, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

41. AstraZeneca admits that AstraZeneca entities market and sell Prilosec® and Nexium® in the United States. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 41, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

42. The allegations set forth in Paragraph 42 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 42, and, therefore, denies same.

43. The allegations set forth in Paragraph 43 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 43, and, therefore, denies same.

44. The allegations set forth in Paragraph 44 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 44, and, therefore, denies same.

45. The allegations set forth in Paragraph 45 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 45, and, therefore, denies same.

46. The allegations set forth in Paragraph 46 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 46, and, therefore, denies same.

47. The allegations set forth in Paragraph 47 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 47, and, therefore, denies same.

48. The allegations set forth in Paragraph 48 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 48, and, therefore, denies same.

49. The allegations set forth in Paragraph 49 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 49, and, therefore, denies same.

50. The allegations set forth in Paragraph 50 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 50, and, therefore, denies same.

51. The allegations set forth in Paragraph 51 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 51, and, therefore, denies same.

52. To the extent Paragraph 52 states legal conclusions, or contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 52.

53. To the extent Paragraph 53 states legal conclusions, or contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that for a period of time beginning in 1994, the entity known as Astra Merck Inc. sold certain products, including Prilosec. AstraZeneca denies the remaining allegations set forth in Paragraph 53.

54. To the extent the Paragraph 54 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 54 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 54 as stated.

55. The allegations set forth in Paragraph 55 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 55, and, therefore, denies same.

56. The allegations set forth in Paragraph 56 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 56, and, therefore, denies same.

57. The allegations set forth in Paragraph 57 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 57, and, therefore, denies same.

58. The allegations set forth in Paragraph 58 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 58, and, therefore, denies same.

59. The allegations set forth in Paragraph 59 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 59, and, therefore, denies same.

60. The allegations set forth in Paragraph 60 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 60, and, therefore, denies same.

61. The allegations set forth in Paragraph 61 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 61, and, therefore, denies same.

62. The allegations set forth in Paragraph 62 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 62, and, therefore, denies same.

63. The allegations set forth in Paragraph 63 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 63, and, therefore, denies same.

64. The allegations set forth in Paragraph 64 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 64, and, therefore, denies same.

65. The allegations set forth in Paragraph 65 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 65, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

66. The allegations set forth in Paragraph 66 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 66, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

67. The allegations set forth in Paragraph 67 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 67, and, therefore, denies same.

68. The allegations set forth in Paragraph 68 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 68, and, therefore, denies same.

69. The allegations set forth in Paragraph 69 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 69, and, therefore, denies same.

70. The allegations set forth in Paragraph 70 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 70, and, therefore, denies same.

71. The allegations set forth in Paragraph 71 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 71, and, therefore, denies same.

72. The allegations set forth in Paragraph 72 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 72, and, therefore, denies same.

73. The allegations set forth in Paragraph 73 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 73, and, therefore, denies same.

74. The allegations set forth in Paragraph 74 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 74, and, therefore, denies same.

75. The allegations set forth in Paragraph 75 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 75, and, therefore, denies same.

76. The allegations set forth in Paragraph 76 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 76, and, therefore, denies same.

77. The allegations set forth in Paragraph 77 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 77, and, therefore, denies same.

78. The allegations set forth in Paragraph 78 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 78, and, therefore, denies same.

79. The allegations set forth in Paragraph 79 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 79, and, therefore, denies same.

80. The allegations set forth in Paragraph 80 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 80, and, therefore, denies same.

81. The allegations set forth in Paragraph 81 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 81, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

82. The allegations set forth in Paragraph 82 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 82, including the undefined, subjective term “substantial revenue,” and, therefore, denies same

83. The allegations set forth in Paragraph 83 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 83, and, therefore, denies same.

84. The allegations set forth in Paragraph 84 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 84, and, therefore, denies same.

85. To the extent the Paragraph 85 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 85 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 85 as stated.

86. To the extent the Paragraph 86 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 86 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 86 as stated.

87. The allegations set forth in Paragraph 87 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 87, and, therefore, denies same.

88. The allegations set forth in Paragraph 88 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 88, and, therefore, denies same.

89. The allegations set forth in Paragraph 89 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 89, and, therefore, denies same.

90. The allegations set forth in Paragraph 90 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 90, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

91. The allegations set forth in Paragraph 91 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 91, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

92. The allegations set forth in Paragraph 92 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 92, and, therefore, denies same.

93. The allegations set forth in Paragraph 93 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 93, and, therefore, denies same.

94. The allegations set forth in Paragraph 94 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 94, and, therefore, denies same.

95. The allegations set forth in Paragraph 95 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 95, and, therefore, denies same.

96. The allegations set forth in Paragraph 96 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 96, and, therefore, denies same.

97. To the extent the Paragraph 97 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 97 as stated.

98. The allegations set forth in Paragraph 98 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 98, and, therefore, denies same.

99. The allegations set forth in Paragraph 99 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca states that the agreement referenced in Paragraph 99 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 99 as stated.

100. To the extent the Paragraph 100 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 100 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 100 as stated.

101. To the extent the Paragraph 101 contains allegations not directed at AstraZeneca, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca states that the agreement referenced in Paragraph 101 speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 101 as stated.

102. The allegations set forth in Paragraph 102 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 102, and, therefore, denies same.

103. The allegations set forth in Paragraph 103 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 103, and, therefore, denies same.

104. The allegations set forth in Paragraph 104 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 104, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

105. The allegations set forth in Paragraph 105 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 105, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

106. The allegations set forth in Paragraph 106 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 106, and, therefore, denies same.

107. The allegations set forth in Paragraph 107 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 107, and, therefore, denies same.

108. The allegations set forth in Paragraph 108 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 108, and, therefore, denies same.

109. The allegations set forth in Paragraph 109 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 109, and, therefore, denies same.

110. The allegations set forth in Paragraph 110 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 110, and, therefore, denies same.

111. The allegations set forth in Paragraph 111 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 111, and, therefore, denies same.

112. The allegations set forth in Paragraph 112 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 112, and, therefore, denies same.

113. The allegations set forth in Paragraph 113 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 113, and, therefore, denies same.

114. The allegations set forth in Paragraph 114 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 114, and, therefore, denies same.

115. The allegations set forth in Paragraph 115 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 115, and, therefore, denies same.

116. The allegations set forth in Paragraph 116 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 116, and, therefore, denies same.

117. The allegations set forth in Paragraph 117 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 117, and, therefore, denies same.

118. The allegations set forth in Paragraph 118 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 118, and, therefore, denies same.

119. The allegations set forth in Paragraph 119 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 119, and, therefore, denies same.

120. The allegations set forth in Paragraph 120 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 120, and, therefore, denies same.

121. The allegations set forth in Paragraph 121 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond,

AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 121, and, therefore, denies same.

122. The allegations set forth in Paragraph 122 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

123. The allegations set forth in Paragraph 123 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 123, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

124. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 124 as stated.

125. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 125 as stated.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. AstraZeneca admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 126 as stated.

127. AstraZeneca admits that Nexium® and Prilosec® are proton pump inhibitor medications approved by the FDA and that their respective clinical pharmacologies are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 127 as stated.

128. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 128, including the undefined, subjective terms “most commercially successful,” top ten best-selling,” and “most dispensed,” and, therefore, denies same.

129. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 129, and, therefore, denies same.

130. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 130, and, therefore, denies same.

131. AstraZeneca admits that the document referenced in Paragraph 131 speaks for itself. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 131, and, therefore, denies same.

B. PPI Products Cause Severe Kidney Injuries

132. AstraZeneca admits that the document referenced in Paragraph 132 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 132 as stated.

133. AstraZeneca denies the allegations set forth in Paragraph 133 as stated.

i. PPI-Induced Acute Interstitial Nephritis ("AIN")

134. AstraZeneca admits that the documents referenced in Paragraph 134 speak for themselves. AstraZeneca otherwise denies the allegations set forth in Paragraph 134 as stated.

135. AstraZeneca admits that the document referenced in Paragraph 135 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 135 as stated.

136. AstraZeneca admits that the document referenced in Paragraph 136 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 136 as stated.

137. AstraZeneca admits that the document referenced in Paragraph 137 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 137 as stated.

138. AstraZeneca admits that the Public Citizen Petition to the FDA is dated August 23, 2011, and that it speaks for itself, but otherwise denies the allegations set forth in Paragraph 138 as stated.

139. AstraZeneca admits that the Public Citizen Petition speaks for itself, but otherwise denies the allegations set forth in Paragraph 139 as stated.

140. AstraZeneca admits that the FDA response to the Public Citizen Petition speaks for itself. AstraZeneca further admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 140 as stated.

141. AstraZeneca admits that the FDA response to the Public Citizen Petition speaks for itself, but otherwise denies the allegations set forth in Paragraph 141 as stated.

142. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for

themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 142 as stated.

143. The allegations set forth in Paragraph 143 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 143 regarding undefined “over-the-counter PPI Products” and “risk information,” and, therefore, denies same.

144. To the extent Paragraph 144 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies such allegations set forth in Paragraph 144 as stated. AstraZeneca denies the remaining allegations set forth in Paragraph 144.

145. The allegations set forth in Paragraph 145 are not directed at AstraZeneca, and therefore no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 145 regarding undefined “over-the-counter PPI Products” and, therefore, denies same.

146. To the extent Paragraph 146 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 146 as stated.

147. To the extent Paragraph 147 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 147 as stated.

148. AstraZeneca admits that the documents referenced in Paragraph 148 speak for themselves. AstraZeneca otherwise denies the allegations set forth in Paragraph 148, including all subparts, as stated.

149. To the extent Paragraph 149 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 149 as stated.

150. To the extent Paragraph 150 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 150 as stated.

151. To the extent Paragraph 151 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 151 as stated.

ii. PPI-Induced Acute Kidney Injury ("AKI")

152. To the extent Paragraph 152 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 152 as stated.

153. AstraZeneca is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 153, including the undefined term “studies” and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 153 as stated.

154. AstraZeneca is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 154, including the undefined term “studies” and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 154 as stated.

155. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 155 regarding undefined “prescription and over-the-counter” PPI Products, and, therefore, denies same.

156. To the extent Paragraph 156 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 156 as stated.

iii. PPI-Induced Chronic Kidney Disease ("CKD")

157. To the extent Paragraph 157 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 157 as stated.

158. To the extent Paragraph 158 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 158 as stated.

159. AstraZeneca admits that the document referenced in Paragraph 159 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 159 as stated.

160. AstraZeneca admits that the document referenced in Paragraph 160 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 160 as stated.

161. AstraZeneca admits that the document referenced in Paragraph 161 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 161 as stated.

162. To the extent Paragraph 162 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 162 as stated.

163. AstraZeneca admits that the document referenced in Paragraph 163 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 163 as stated.

164. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 164 as stated.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. To the extent Paragraph 165 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 165 as stated.

166. To the extent Paragraph 166 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 166 as stated.

167. AstraZeneca is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 167, including the undefined term “studies” and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 169 as stated.

168. To the extent Paragraph 168 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 168 as stated.

169. AstraZeneca denies the allegations set forth in Paragraph 169.

170. AstraZeneca denies the allegations set forth in Paragraph 170.

171. AstraZeneca is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 171, including the undefined term “studies” and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 173 as stated.

172. To the extent Paragraph 172 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 172 as stated.

173. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package

inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 173 as stated.

D. Safer Alternatives to PPIs

174. To the extent Paragraph 174 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 176, including all subparts.

175. AstraZeneca admits that the document referenced in Paragraph 175 speaks for itself. AstraZeneca otherwise denies the allegations set forth in Paragraph 175 as stated.

176. To the extent Paragraph 176 states legal conclusions, no response is required. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 176.

E. Injuries Resulting from PPI Products

177. AstraZeneca denies the allegations set forth in Paragraph 177.

178. AstraZeneca denies the allegations set forth in Paragraph 178.

179. AstraZeneca denies the allegations set forth in Paragraph 179.

180. AstraZeneca denies the allegations set forth in Paragraph 180.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

181. AstraZeneca denies the allegations set forth in Paragraph 181.

182. AstraZeneca denies the allegations set forth in Paragraph 182.

183. AstraZeneca denies the allegations set forth in Paragraph 183.

184. AstraZeneca denies the allegations set forth in Paragraph 184.

185. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 185 regarding Plaintiff and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 185 and denies it breached any duty.

186. To the extent Paragraph 186 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies it breached any duty and denies the remaining allegations set forth in Paragraph 186 as stated.

187. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 187.

188. AstraZeneca denies the allegations set forth in Paragraph 188.

189. AstraZeneca denies the allegations set forth in Paragraph 189 as stated.

190. AstraZeneca denies the allegations set forth in Paragraph 190.

191. AstraZeneca denies the allegations set forth in Paragraph 191.

192. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the

law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 192.

193. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 193.

194. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 194.

195. To the extent Paragraph 195 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca

fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 195.

G. Defendants Violations of Federal Law

196. AstraZeneca denies the allegations set forth in Paragraph 196.

197. AstraZeneca denies the allegations set forth in Paragraph 197, including all subparts, and denies it breached any duty.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. To the extent Paragraph 198 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 198 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

199. To the extent Paragraph 199 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 199.

200. To the extent Paragraph 200 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 200.

201. To the extent Paragraph 201 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 201.

202. To the extent Paragraph 202 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 202.

203. To the extent Paragraph 203 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 203 and denies it breached any duty.

204. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States and that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 204 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 204.

205. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 205 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 205.

206. To the extent Paragraph 206 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 206, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 206.

207. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 207 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 207.

208. To the extent Paragraph 208 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 208 and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 208.

209. To the extent Paragraph 209 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 209, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 209.

210. To the extent Paragraph 210 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 210, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 210.

211. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 211 as to the actions of others and including the undefined term “studies or information” and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 211.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY

212. To the extent Paragraph 212 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 212 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

213. AstraZeneca denies the allegations set forth in Paragraph 213.

214. AstraZeneca denies the allegations set forth in Paragraph 214.

215. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 215 as stated.

216. To the extent Paragraph 216 states legal conclusions, no response is required. To the extent a response is required, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 216, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 216 as stated.

217. AstraZeneca denies the allegations set forth in Paragraph 217.

218. AstraZeneca denies the allegations set forth in Paragraph 218.

219. AstraZeneca denies the allegations set forth in Paragraph 219.

220. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 220.

221. AstraZeneca denies the allegations set forth in Paragraph 221.

222. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 222, and, therefore, denies same.

223. AstraZeneca denies the allegations set forth in Paragraph 223.

224. To the extent Paragraph 224 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 224 as stated and denies it breached any duty.

225. AstraZeneca denies the allegations set forth in Paragraph 225.

226. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 226.

227. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 227.

228. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 228.

229. AstraZeneca denies the allegations set forth in Paragraph 229.

230. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 230.

231. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 231.

232. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 232.

233. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 233.

234. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 234.

235. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 235, and, therefore, denies same.

236. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 236, and, therefore, denies same.

237. AstraZeneca denies the allegations set forth in Paragraph 237, including all subparts.

238. AstraZeneca denies the allegations set forth in Paragraph 238.

239. AstraZeneca denies the allegations set forth in Paragraph 239.

240. AstraZeneca denies the allegations set forth in Paragraph 240.

241. AstraZeneca denies the allegations set forth in Paragraph 241.

242. AstraZeneca denies the allegations set forth in Paragraph 242.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 242. AstraZeneca also requests a trial by jury.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

243. To the extent Paragraph 243 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 243 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

244. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 244.

245. AstraZeneca denies the allegations set forth in Paragraph 245.

246. AstraZeneca denies the allegations set forth in Paragraph 246.

247. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 247, and, therefore, denies same.

248. AstraZeneca denies the allegations set forth in Paragraph 248.

249. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 249, and, therefore, denies same.

250. AstraZeneca denies the allegations set forth in Paragraph 250

251. AstraZeneca denies the allegations set forth in Paragraph 251.

252. AstraZeneca denies the allegations set forth in Paragraph 252.

253. AstraZeneca denies the allegations set forth in Paragraph 253.

254. AstraZeneca denies the allegations set forth in Paragraph 254.

255. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 255 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 255.

256. AstraZeneca denies the allegations of Paragraph 256.

257. AstraZeneca denies the allegations of Paragraph 257.

258. AstraZeneca denies the allegations set forth in Paragraph 258.

259. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 259 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 259.

260. AstraZeneca denies the allegations set forth in Paragraph 260.

261. AstraZeneca denies the allegations set forth in Paragraph 261.

262. AstraZeneca denies the allegations set forth in Paragraph 262.

263. AstraZeneca denies the allegations set forth in Paragraph 263.

264. AstraZeneca denies the allegations set forth in Paragraph 264.

265. AstraZeneca denies the allegations set forth in Paragraph 265.

266. AstraZeneca denies the allegations set forth in Paragraph 266.

267. AstraZeneca denies the allegations set forth in Paragraph 267.

268. AstraZeneca denies the allegations set forth in Paragraph 268.

269. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 269 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 269.

270. AstraZeneca denies the allegations set forth in Paragraph 270.

271. AstraZeneca denies the allegations set forth in Paragraph 271.

272. AstraZeneca denies the allegations set forth in Paragraph 272.

273. AstraZeneca denies the allegations set forth in Paragraph 273.

274. AstraZeneca denies the allegations set forth in Paragraph 274.

275. AstraZeneca denies the allegations set forth in Paragraph 275.

276. AstraZeneca denies the allegations set forth in Paragraph 276.

277. AstraZeneca denies the allegations set forth in Paragraph 277.

278. AstraZeneca denies the allegations set forth in Paragraph 278.

279. AstraZeneca denies the allegations set forth in Paragraph 279.

280. AstraZeneca denies the allegations set forth in Paragraph 280.

281. AstraZeneca denies the allegations set forth in Paragraph 281.

282. AstraZeneca denies the allegations set forth in Paragraph 282.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 282. AstraZeneca also requests a trial by jury.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. To the extent Paragraph 283 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 283 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

284. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 284.

285. AstraZeneca denies the allegations set forth in Paragraph 285.

286. To the extent Paragraph 286 states legal conclusions, no response is required. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 286 as stated and denies it breached any duty.

287. AstraZeneca denies the allegations set forth in Paragraph 287.

288. AstraZeneca denies the allegations set forth in Paragraph 288.

289. To the extent Paragraph 289 states legal conclusions, no response is required. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 289 as stated.

290. AstraZeneca denies the allegations set forth in Paragraph 290.

291. To the extent Paragraph 291 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 291 and denies it breached any duty.

292. AstraZeneca denies the allegations set forth in Paragraph 292.

293. AstraZeneca denies the allegations set forth in Paragraph 293.

294. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 294, and, therefore, denies same.

295. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 295 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 295.

296. To the extent Paragraph 296 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 296 as stated.

297. AstraZeneca denies the allegations set forth in Paragraph 297.

298. To the extent Paragraph 298 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set

forth in Paragraph 298, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 298.

299. To the extent Paragraph 299 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 299 and denies it breached any duty.

300. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 300 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 300.

301. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca further admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 301.

302. To the extent Paragraph 302 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 302 and denies it breached any duty.

303. AstraZeneca admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 303.

304. AstraZeneca denies the allegations set forth in Paragraph 304.

305. AstraZeneca denies the allegations set forth in Paragraph 305.

306. To the extent Paragraph 306 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 306, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 306.

307. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 307 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 307.

308. AstraZeneca denies the allegations set forth in Paragraph 308.

309. AstraZeneca denies the allegations set forth in Paragraph 309.

310. AstraZeneca denies the allegations set forth in Paragraph 310.

311. AstraZeneca denies the allegations set forth in Paragraph 311.

312. AstraZeneca denies the allegations set forth in Paragraph 312.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 312. AstraZeneca also requests a trial by jury.

COUNT IV
NEGLIGENCE

313. To the extent Paragraph 313 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 315 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

314. To the extent Paragraph 314 states legal conclusions, no response is required. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 314 as stated and denies it breached any duty.

315. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 315 and denies it breached any duty.

316. AstraZeneca denies the allegations set forth in Paragraph 316, including all subparts.

317. AstraZeneca denies the allegations set forth in Paragraph 317.

318. AstraZeneca denies the allegations set forth in Paragraph 318.

319. AstraZeneca denies the allegations set forth in Paragraph 319.

320. AstraZeneca denies the allegations set forth in Paragraph 320.

321. AstraZeneca denies the allegations set forth in Paragraph 321.

322. AstraZeneca denies the allegations set forth in Paragraph 322.

323. AstraZeneca admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 323.

324. AstraZeneca denies the allegations set forth in Paragraph 324.

325. AstraZeneca denies the allegations set forth in Paragraph 325.

326. AstraZeneca denies the allegations set forth in Paragraph 326.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 326. AstraZeneca also requests a trial by jury.

COUNT V
NEGLIGENCE PER SE

327. To the extent Paragraph 327 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 327 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

328. AstraZeneca denies the allegations set forth in Paragraph 328.

329. To the extent Paragraph 329 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 329 as stated.

330. AstraZeneca denies the allegations set forth in Paragraph 330.

331. To the extent Paragraph 331 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 331 as stated.

332. To the extent Paragraph 332 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 332 as stated.

333. AstraZeneca denies the allegations set forth in Paragraph 333.

334. AstraZeneca denies the allegations set forth in Paragraph 334.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 334. AstraZeneca also requests a trial by jury.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. To the extent Paragraph 335 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 335 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

336. AstraZeneca denies the allegations set forth in Paragraph 336 as stated and denies it breached any duty.

337. AstraZeneca denies the allegations set forth in Paragraph 337.

338. AstraZeneca denies the allegations set forth in Paragraph 338.

339. AstraZeneca denies the allegations set forth in Paragraph 339.

340. AstraZeneca denies the allegations set forth in Paragraph 340.

341. AstraZeneca denies the allegations set forth in Paragraph 341.

342. AstraZeneca denies the allegations set forth in Paragraph 342.

343. To the extent Paragraph 343 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 343, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 343.

344. AstraZeneca denies the allegations set forth in Paragraph 344.

345. To the extent Paragraph 345 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 345.

346. AstraZeneca denies the allegations set forth in Paragraph 346.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 346. AstraZeneca also requests a trial by jury.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.72

347. To the extent Paragraph 347 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 347 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

348. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 348 as stated.

349. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 349.

350. AstraZeneca denies the allegations set forth in Paragraph 350.

351. To the extent Paragraph 351 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 351, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 351.

352. AstraZeneca denies the allegations set forth in Paragraph 352.

353. AstraZeneca denies the allegations set forth in Paragraph 353.

354. AstraZeneca denies the allegations set forth in Paragraph 354.

355. AstraZeneca denies the allegations set forth in Paragraph 355.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 355. AstraZeneca also requests a trial by jury.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. To the extent Paragraph 356 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 356 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

357. To the extent Paragraph 357 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 357.

358. To the extent Paragraph 358 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 358.

359. To the extent Paragraph 359 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 359.

360. To the extent Paragraph 360 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. AstraZeneca further admits that any and

all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 360.

361. AstraZeneca denies the allegations set forth in Paragraph 361.

362. To the extent Paragraph 362 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 362, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 362.

363. AstraZeneca denies the allegations set forth in Paragraph 363.

364. AstraZeneca denies the allegations set forth in Paragraph 364, including all subparts.

365. AstraZeneca denies the allegations set forth in Paragraph 365.

366. To the extent Paragraph 366 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 366, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 366.

367. AstraZeneca denies the allegations set forth in Paragraph 367.

368. AstraZeneca denies the allegations set forth in Paragraph 368.

369. To the extent Paragraph 369 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 369.

370. To the extent Paragraph 370 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 370, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 370.

371. To the extent Paragraph 371 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 371, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 371.

372. AstraZeneca denies the allegations set forth in Paragraph 372.

373. AstraZeneca denies the allegations set forth in Paragraph 373.

374. AstraZeneca denies the allegations set forth in Paragraph 374.

375. AstraZeneca denies the allegations set forth in Paragraph 375.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 375. AstraZeneca also requests a trial by jury.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. To the extent Paragraph 376 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 376 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

377. To the extent Paragraph 377 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations in Paragraph 377.

378. To the extent Paragraph 378 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 378.

379. AstraZeneca denies the allegations set forth in Paragraph 379.

380. To the extent Paragraph 380 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 380, and, therefore, denies same. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 380.

381. To the extent Paragraph 381 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set

forth in Paragraph 381, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 381.

382. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca otherwise denies the allegations set forth in Paragraph 382.

383. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the allegations set forth in Paragraph 383.

384. AstraZeneca denies the allegations set forth in Paragraph 384.

385. To the extent Paragraph 385 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 385, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 385.

386. AstraZeneca denies the allegations set forth in Paragraph 386.

387. AstraZeneca denies the allegations set forth in Paragraph 387.

388. AstraZeneca denies the allegations set forth in Paragraph 388.

389. AstraZeneca denies the allegations set forth in Paragraph 389.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 389. AstraZeneca also requests a trial by jury.

COUNT X
NEGLIGENT MISREPRESENTATION

390. To the extent Paragraph 390 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 390 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

391. AstraZeneca denies the allegations set forth in Paragraph 391.

392. To the extent Paragraph 392 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 392 and denies that it breached any duty.

393. AstraZeneca admits that AstraZeneca entities market and sell Nexium® and Prilosec® in the United States. AstraZeneca denies the remaining allegations in Paragraph 393.

394. AstraZeneca denies the allegations set forth in Paragraph 394.

395. AstraZeneca denies the allegations set forth in Paragraph 395.

396. AstraZeneca denies the allegations set forth in Paragraph 396.

397. AstraZeneca denies the allegations set forth in Paragraph 397.

398. To the extent Paragraph 398 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 398, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 398.

399. AstraZeneca denies the allegations set forth in Paragraph 399.

400. AstraZeneca denies the allegations set forth in Paragraph 400.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 400. AstraZeneca also requests a trial by jury.

COUNT XI
FRAUD AND FRAUDULENT MISREPRESENTATION

401. To the extent Paragraph 401 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 401 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

402. AstraZeneca denies the allegations set forth in Paragraph 402.

403. AstraZeneca admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. AstraZeneca denies the remaining allegations set forth in Paragraph 403 as stated.

404. AstraZeneca denies the allegations set forth in Paragraph 404.

405. AstraZeneca denies the allegations set forth in Paragraph 405.

406. AstraZeneca denies the allegations set forth in Paragraph 406.

407. AstraZeneca denies the allegations set forth in Paragraph 407.

408. To the extent Paragraph 408 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 408, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 408.

409. To the extent Paragraph 409 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 409, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 409.

410. AstraZeneca denies the allegations set forth in Paragraph 410.

411. AstraZeneca denies the allegations set forth in Paragraph 411.

412. AstraZeneca denies the allegations set forth in Paragraph 412.

413. AstraZeneca denies the allegations set forth in Paragraph 413.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 413. AstraZeneca also requests a trial by jury.

COUNT XII
GROSS NEGLIGENCE

414. To the extent Paragraph 414 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 414 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

415. AstraZeneca denies the allegations set forth in Paragraph 415, including all subparts.

416. AstraZeneca admits that Plaintiff seeks damages, but denies Plaintiff is entitled to the relief sought. AstraZeneca denies the remaining allegations set forth in Paragraph 416.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 416. AstraZeneca also requests a trial by jury.

COUNT XIII
FRAUDULENT CONCEALMENT

417. To the extent Paragraph 417 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 417 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

418. AstraZeneca denies the allegations set forth in Paragraph 418.

419. AstraZeneca denies the allegations set forth in Paragraph 419.

420. AstraZeneca denies the allegations set forth in Paragraph 420.

421. To the extent Paragraph 421 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 421, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 421.

422. AstraZeneca denies the allegations set forth in Paragraph 422.

423. To the extent Paragraph 423 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 423, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 423.

424. AstraZeneca denies the allegations set forth in Paragraph 424.

425. To the extent Paragraph 425 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 425 as stated and denies it breached any duty.

426. To the extent Paragraph 426 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 426 as stated and denies it breached any duty.

427. To the extent Paragraph 427 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 427 and denies it breached any duty.

428. To the extent Paragraph 428 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 428, and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 428.

429. AstraZeneca denies the allegations set forth in Paragraph 429.

430. AstraZeneca denies the allegations set forth in Paragraph 430.

431. AstraZeneca denies the allegations set forth in Paragraph 431.

432. AstraZeneca denies the allegations set forth in Paragraph 432.

433. AstraZeneca denies the allegations set forth in Paragraph 433.

434. AstraZeneca denies the allegations set forth in Paragraph 434.

435. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 435 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 435.

436. AstraZeneca denies the allegations set forth in Paragraph 436.

437. AstraZeneca denies the allegations set forth in Paragraph 437.

438. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 438 as to the actions of others and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 438.

439. AstraZeneca denies the allegations set forth in Paragraph 439.

440. AstraZeneca denies the allegations set forth in Paragraph 440.

441. AstraZeneca denies the allegations set forth in Paragraph 441.

AstraZeneca denies the allegations set forth in the unnumbered Paragraph immediately following Paragraph 441 and denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following. AstraZeneca also requests a trial by jury.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. To the extent Paragraph 442 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 442 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

443. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff’s use of "PPI Products" and, therefore denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 443.

444. AstraZeneca denies the allegations set forth in Paragraph 444.

445. AstraZeneca denies the allegations set forth in Paragraph 445.

446. AstraZeneca denies the allegations set forth in Paragraph 446.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 446. AstraZeneca also requests a trial by jury.

RESPONSE TO PRAYER FOR RELIEF

In response to the Paragraph entitled “Prayer for Relief,” AstraZeneca denies that Plaintiff is entitled to any of the relief requested.

DEFENSES

Discovery and investigation may reveal that one or more of the following defenses should be available to AstraZeneca in this matter. AstraZeneca accordingly preserves the right to assert these separate defenses. Upon completion of discovery, if facts warrant, AstraZeneca may withdraw any of these defenses as may be appropriate. AstraZeneca further reserves the right to amend this Answer to assert additional defenses and other claims as discovery proceeds.

By alleging the matters set forth below, AstraZeneca does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, nothing stated herein is intended or shall be construed as an acknowledgment that any particular issue or subject necessarily is relevant to Plaintiff’s allegations.

If necessary and/or in the alternative, AstraZeneca raises the following defenses available in Ohio or in any other State or Commonwealth of the United States, under statute or common law (hereinafter “state”), whose laws might be deemed controlling in this case, but reserves the right to amend its Answer to raise any additional defenses which it may have against Plaintiff’s claims:

1. Plaintiff's claims and causes of action are barred by the applicable statute(s) of limitation, the applicable statute(s) of repose, and/or may be otherwise untimely.

2. Plaintiff fails to state a claim upon which relief can be granted as required by Ohio Rule of Civil Procedure 12(B).

3. This Court lacks personal jurisdiction over AstraZeneca with respect to Plaintiff's claims, and thus the Complaint should be dismissed under Rule 12(B)(2) of the Civil Rules.

4. Plaintiff fails to plead claims against AstraZeneca with sufficient particularity as required by Civil Rule 9(B).

5. Nexium® and Prilosec® are pharmaceuticals which were available only upon prescription of a licensed physician. Any warnings that AstraZeneca gave were transmitted to prescribing physicians and/or healthcare providers. Under Ohio or other applicable state law, AstraZeneca fulfilled its obligation to provide adequate warnings and instructions and Plaintiff's claims are therefore barred pursuant to the learned intermediary doctrine.

6. If Plaintiff sustained the injuries or damages as alleged, said injuries and expenses were directly and proximately caused by the acts and omissions (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more parties other than AstraZeneca over whom AstraZeneca had no supervision or control and for whose actions and omissions AstraZeneca has no legal responsibility. AstraZeneca is not liable for negligence and violated no duty that may have been owed to Plaintiff.

7. AstraZeneca's activities conformed to all state and federal statutes, regulations, and industry standards based upon the state of the knowledge that existed at the time.

8. Plaintiff's recovery is barred and/or should be reduced under the applicable law because of Plaintiff's comparative negligence or fault, culpable conduct, intentional acts, assumption of risk, and/or want of care.

9. Plaintiff's injuries and damages, if any, resulted from an intervening or superseding cause or causes and any act or omission on the part of AstraZeneca was not the proximate and/or competent producing cause of such alleged injuries or damages.

10. AstraZeneca did not sell or distribute products directly to Plaintiff. Plaintiff's claims are, therefore, barred by lack of privity between Plaintiff and AstraZeneca.

11. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards and techniques utilized with respect to the design, manufacture, marketing, distribution, and sale of Nexium® and Prilosec®, including adequate warnings and instructions with respect to the products' use included in the product's package inserts and other literature conformed to the applicable state of the art. The products in question, including their FDA-approved labeling, complied with the state of scientific and medical knowledge available to AstraZeneca at the time of its manufacture, distribution, and sale.

12. With respect to each and every purported cause of action, the acts of AstraZeneca were at all times done in good faith and without malice.

13. Plaintiff's claims are barred in whole or in part under comment *k* to Section 402A of the Restatement (Second) of Torts.

14. Plaintiff's claims are barred in whole or in part because AstraZeneca provided legally adequate "directions or warnings" as to the use of the products at issue and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment *j* to Section 402A of the Restatement (Second) of Torts.

15. Plaintiff's claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment *f* to Section 6, of the Restatement (Third) of Torts: Products Liability.

16. With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments *j* and *k* to Section 402A of the Restatement (Second) of Torts relegate Plaintiff's claims to a negligence cause of action.

17. Nexium® and Prilosec® complied with all applicable state and federal statutes regarding the products in question, including product safety regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged in by the Complaint. The products at issue were reasonably fit, suitable, and safe for their respective intended uses, demonstrating that due care was exercised with respect to the design, manufacture, testing, marketing, distribution, and sale of Nexium® and Prilosec®. In the event that Plaintiff's claims are not barred, AstraZeneca is entitled to a presumption that the products in question are free from any defect or defective condition as the plans or design for the products or the methods and techniques of manufacturing, inspecting, and testing the products were in conformity with government standards established for the drug industry that were in existence at the time the plans or designs for the products or the methods and techniques of manufacturing, inspecting, and testing the products were adopted.

18. Plaintiff's claims are barred because Nexium® and Prilosec® were neither defective nor unreasonably dangerous in their design, manufacture, distribution, or marketing, and were reasonably safe and reasonably fit for their intended use, thereby barring Plaintiff's recovery.

19. If Plaintiff sustained the injuries or damages as alleged, said injuries or damages were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drugs Nexium® and/or Prilosec® thereby barring Plaintiff's recovery against AstraZeneca.

20. Plaintiff's claims are barred to the extent Plaintiff knew the condition of Nexium® and/or Prilosec®, appreciated the risks of injury flowing from Nexium® and/or Prilosec® use, and nevertheless proceeded to use Nexium® and/or Prilosec® without regard to the danger of such risks. As a result, Plaintiff gave informed consent and/or assumed the risk of injury of which they now complain.

21. The extent of any risk associated with the use of the products at issue, the existence of which is not admitted, was, at the time of the distribution of said products by AstraZeneca, unknown and could not have been known by the use of ordinary care.

22. The public interest in the benefit and availability of the products which are the subject matter of this action precludes liability, if any, resulting from any activities undertaken by AstraZeneca, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there exists a risk inherent in the subject products, then such risk, if any, is outweighed by the benefit of the products.

23. Plaintiff's failure to warn claim is barred given that AstraZeneca had no duty to warn of risks of which they neither knew nor should have known at the time Nexium® and Prilosec® were designed, distributed, and manufactured.

24. Plaintiff's injuries and damages, if any, were the result of an idiosyncratic reaction that AstraZeneca could not have reasonably foreseen, thereby barring Plaintiff's recovery.

25. Plaintiff's claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or contemporaneous) unrelated to any conduct of AstraZeneca or condition of the products, Nexium® and Prilosec®, thereby barring Plaintiff's recovery.

26. Plaintiff has not sustained an ascertainable loss of property or money, nor any actual injury or damages.

27. Plaintiff's claims are barred under the doctrine of economic loss.

28. Plaintiff failed to mitigate damages.

29. To the extent applicable, Plaintiff's breach of warranty claims are barred because there is no privity of contract between Plaintiff and AstraZeneca; Plaintiff failed to provide AstraZeneca with reasonable or adequate notice of the alleged breach of any such purported warranty pursuant to the applicable Uniform Commercial Code; Plaintiff did not reasonably rely upon such purported warranty; Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such purported warranty; and/or the purported warranty was appropriately disclaimed, excluded, or modified.

30. AstraZeneca's advertisements and labeling with respect to the products which are the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution and applicable state law.

31. AstraZeneca is entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

32. AstraZeneca denies any liability, but if AstraZeneca is ultimately found liable to Plaintiff, then it shall only be liable for their equitable share of Plaintiff's recovery since any liability which would be found against AstraZeneca will be insufficient to impose joint liability.

33. If Plaintiff recovers from AstraZeneca, AstraZeneca is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiff's alleged damages.

34. Any verdict or judgment rendered against AstraZeneca must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part, for any past or future claimed economic loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

35. Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences.

36. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, AstraZeneca's liability, if any, should be precluded or reduced accordingly.

37. To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, unless AstraZeneca's liability for punitive damages and the appropriate amount of punitive damages is required to be established by clear and convincing evidence, any award of punitive damages would violate AstraZeneca's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the United States

Constitution and under any applicable state constitution, and would be improper under the common law, public policies, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

38. To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, any such claim of Plaintiff for punitive damages against AstraZeneca cannot be maintained because there was no act or omission by AstraZeneca that was oppressive, fraudulent, or malicious. Additionally, any award of punitive damages under the applicable law would be unlawful and unauthorized, and would be void for vagueness, both facially and as applied, as a result of, among other deficiencies, the absence of adequate notice of what conduct is subject to punishment; the absence of adequate notice of what punishment may be imposed; and the absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that a jury may impose, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, under any applicable state constitution, and the common law and public policies of any applicable state.

39. To the extent Plaintiff seeks recovery of punitive damages against AstraZeneca, any such claim of Plaintiff for punitive damages against AstraZeneca cannot be maintained because any award of punitive damages under the applicable law would be by a jury that (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of

punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including residence, wealth, and corporate status of AstraZeneca, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is permitted to award punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any, (7) is not subject to adequate, independent, de novo trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards and in conformity with the United States Constitution as amended or any applicable state constitution. Any such verdict would violate AstraZeneca's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process and equal protection provisions of any applicable state constitution, and would be improper under the common law and public policies of that state.

40. Additionally, punitive damages may not be recovered to the extent such damages are: (1) imposed where state law is impermissibly vague, imprecise, or inconsistent, (2) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, or (3) imposed on the basis of anything other than AstraZeneca's conduct within the applicable state, or in any other way subjecting AstraZeneca to impermissible multiple punishment for the same alleged wrong.

41. To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, any award of punitive damages based on anything other than AstraZeneca's

conduct in connection with the design, manufacture, and sale of Nexium® and Prilosec® would violate the due process clause of the Fourteenth Amendment of the United States Constitution and the due process provisions of the Ohio state constitution, and would be improper under the common law and public policies of that state, because any other judgment for punitive damages in this case cannot protect AstraZeneca against impermissible punishment for the same wrong and against punishment for extraterritorial conduct, including conduct that is lawful in states other than the applicable state. In addition, any award would violate principles of comity under the laws of that state.

42. AstraZeneca incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny.

43. AstraZeneca assert the provisions of all applicable statutory caps on damages of any sort, including compensatory, punitive, non-economic or exemplary damages, under all applicable regulations and/or laws.

44. There was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff or reduced the alleged risk, without substantially impairing the usefulness, safety, efficacy, or intended purpose of Nexium® and Prilosec®, thereby barring Plaintiff's recovery.

45. Plaintiff's purported allegations of misrepresentation fail to state a claim for which relief may be granted. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

46. The AstraZeneca products at issue have been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and regulations promulgated thereunder. Therefore, Plaintiff's claims predicated on state tort law and alleging that Nexium® and/or Prilosec® are unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

47. To the extent that Plaintiff asserts claims based on AstraZeneca's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

48. Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating drugs, including the product at issue, and is specifically charged with determining the content of warnings and labeling for drugs.

49. Plaintiff's claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

50. AstraZeneca denies that Nexium® and/or Prilosec® were or are unreasonably dangerous or defective, not fit for its intended, ordinary purpose, or that such products created any liability under Ohio state law.

51. Loss of consortium claims must fail to the extent the allegedly injured spouse's claims fail, as such claims are derivative.

52. No act or omission by AstraZeneca was the proximate cause, contributing cause, or otherwise a cause of any damages alleged by Plaintiff. The negligence of other persons or entities who are not parties to this suit was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. AstraZeneca anticipate that more specific information regarding the identity and potential liability of these non-parties will be developed during discovery.

53. To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate AstraZeneca's rights under the United States Constitution.

54. Plaintiff received all or substantially all of the benefit from the subject products that Plaintiff hoped and intended to receive, and to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from AstraZeneca must be correspondingly barred or reduced.

55. Plaintiff's claims are barred by laches, waiver, accord and satisfaction, payment, release, res judicata, estoppel, spoliation of evidence, statutory and regulatory compliance, and/or the applicability of arbitration and award.

56. Plaintiff's claims may be subject to dismissal or stay on the grounds of *forum non conveniens*.

57. Plaintiff is not entitled to recover attorneys' fees under any applicable law.

58. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to assert them.

59. If Plaintiff was injured by Nexium® and/or Prilosec®, those injuries occurred because the product(s) was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and in disregard of instructions and directions regarding its use. Such misuse was not reasonably foreseeable to AstraZeneca.

60. AstraZeneca denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of AstraZeneca, or at the instruction or subject to the control of AstraZeneca with regard to any of the actions described in the Complaint; thus, AstraZeneca is not liable for any acts or omissions of such third parties as a matter of law.

61. AstraZeneca avers that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

62. Plaintiff's claims are barred, in whole or in part, because AstraZeneca's advertisements and labeling with respect to Nexium® and Prilosec® were not false or misleading and, therefore, constitute protected commercial speech under the First Amendment of the United States Constitution and Section 11, Article I of the Ohio Constitution.

63. If Plaintiff sustained the injuries or incurred the expenses alleged, they may have been caused, in whole or in part, by operation of nature or by an act of God or other intervening causes.

64. No act or omission of AstraZeneca was malicious, willful, wanton, reckless, grossly negligent or intentional and, therefore, any award of punitive damages is barred.

65. AstraZeneca incorporates by reference each defense asserted by any other Defendant.

66. AstraZeneca is entitled to all protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in each case.

67. AstraZeneca hereby raises and preserves the defense of improper venue.

68. Plaintiff fails to state a claim to the extent that Defendants did not manufacture or distribute the product allegedly ingested by Plaintiff.

69. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code 2307.71 through 2307.81, and AstraZeneca hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

70. AstraZeneca hereby pleads all available defenses and principles as set forth in Ohio Rev. Code 2307.22-2307.29.

71. Plaintiff's claims are barred because Nexium® and Prilosec® are "ethical drugs" as defined by Ohio Rev. Code 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.

72. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in O.R.C. 2315.22, *et seq.* and 2315.32-2315.36.

73. Plaintiff's recovery as against AstraZeneca should be barred in accordance with Ohio Rev. Code 2307.78.

74. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code 2315.18 and 2315.21.

75. Plaintiff's right to recover damages, if any, is statutorily limited by Ohio's wrongful death statute, Ohio Rev. Code 2125.01 through 2125.04.

76. Plaintiff's claims for punitive or exemplary damages as set forth in the complaint are barred by Ohio Rev. Code 2307.80(C).

77. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code 2307.71 through 2307.81.

78. Ohio's Consumer Sales Practices Act, Ohio Rev. Code 1345.12(C), specifically precludes claims for personal injury or death.

79. Plaintiff fails to state a claim for relief under Ohio Rev. Code 1345.01, *et seq.*

80. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

81. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

82. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code 2307.711.

83. All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct AstraZeneca had no reason to anticipate and for whose conduct AstraZeneca is not and were not responsible. Ohio Revised Code 2307.22, *et seq.*

84. The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code 2307.23.

85. One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Rev. Code 2307.71 through 2307.80, 2315.18, 2315.21, et al.

86. Plaintiff's design defect claims fail under Ohio Rev. Code 2307.75(D) because adequate warning and instruction were provided under Ohio Rev. Code 2307.76 concerning any unavoidably unsafe aspects of the product.

87. Plaintiff's design defect claims fail under Ohio Rev. Code 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

88. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Rev. Code 2307.75(F).

89. Plaintiff's inadequate warning claims are barred under Ohio Rev. Code 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

WHEREFORE, AstraZeneca demands judgment in its favor and against Plaintiff, dismissing the Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and further relief as the Court deems just and necessary.

Respectfully submitted,

ICE MILLER LLP

/s/ Daniel M. Anderson

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Pharmaceuticals LP, AstraZeneca LP and Merck
Sharp & Dohme Corporation*

JURY DEMAND

AstraZeneca hereby demands a jury trial on all claims so triable in this action.

/s/ Daniel M. Anderson

Daniel M. Anderson

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was filed electronically on August 2, 2019, and a true and accurate copy was served via electronic mail the same day upon the attached Master Service List.

/s/ Daniel M. Anderson

Ohio PPI Cases Master Service List

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CO\6199844.1

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A BEHYMER,

Plaintiff,

v.

ABBOTT LABORATORIES, et al.,

Defendants.

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Civil Action No.: A1902638

**JURY DEMAND ENDORSED
HEREON**

**ANSWER AND DEFENSES OF MERCK SHARP & DOHME CORPORATION TO
PLAINTIFF'S COMPLAINT AND JURY DEMAND**

Defendant Merck Sharp & Dohme Corporation, incorrectly named as Merck & Co., Inc. d/b/a Merck Sharp & Dohme Corporation, by counsel, hereby answers and responds to Plaintiff's Complaint and Jury Demand ("Complaint"). Merck Sharp & Dohme Corporation (herein referred to as "Merck") responds herein to the allegations in the Complaint insofar as such allegations pertain to Merck. Except as otherwise expressly set forth below, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations refer or relate to any other defendant, person or entity. Any allegations, averments, contentions or statements in the Complaint not specifically and unequivocally admitted in this Answer are denied. Merck responds to each of the paragraphs of the Complaint as follows:

NATURE OF THE ACTION¹

1. Merck admits that Plaintiff has attempted to assert a cause of action for personal injuries, but denies that Plaintiff is entitled to the relief sought. Merck is without knowledge or

¹ Merck has utilized the headings contained in Plaintiff's Complaint. To the extent Plaintiff's headings set for legal or factual allegations that require Merck to respond, Merck denies the allegations set forth therein.



information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint based on Plaintiff's personal knowledge and belief, and therefore denies those allegations. Merck denies all remaining allegations in Paragraph 1 of the Complaint.

2. Because there are no legal or factual allegations contained in Paragraph 2, no response is required. To the extent Merck may be required to respond, Merck denies the allegations of Paragraph 2.

3. Merck denies the allegations set forth in Paragraph 3.

4. Merck admits that Plaintiff has attempted to assert a cause of action for personal injuries, but denies the remaining allegations set forth in Paragraph 4.

5. Merck admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 5 as stated.

PARTIES, JURISDICTION & VENUE

6. The allegations in Paragraph 6 of the Complaint are allegations of conclusions of law to which no response is required or necessary. To the extent a response is required or necessary, Merck admits only that Plaintiff alleges in this Complaint that the amount in controversy alleged exceeds the sum of \$25,000 exclusive of interest and costs. Merck is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6 of the Complaint, and therefore denies those allegations.

I. PLAINTIFF

7. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint, including all sub-parts, regarding Plaintiff's residency, Plaintiff's alleged use of PPIs, and the conditions Plaintiff allegedly was

diagnosed with, and therefore denies those allegations. Merck denies all remaining allegations in Paragraph 7.

II. DEFENDANTS

8. The allegations set forth in Paragraph 8 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 8, and, therefore, denies same.

9. The allegations set forth in Paragraph 9 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 9, and, therefore, denies same.

10. The allegations set forth in Paragraph 10 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10, and, therefore, denies same.

11. The allegations set forth in Paragraph 11 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 11, and, therefore, denies same.

12. The allegations set forth in Paragraph 12 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12, and, therefore, denies same.

13. The allegations set forth in Paragraph 13 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 13, and, therefore, denies same.

14. The allegations set forth in Paragraph 14 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 14 and, therefore, denies same.

15. The allegations set forth in Paragraph 15 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 15, and, therefore, denies same.

16. The allegations set forth in Paragraph 16 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 16, and, therefore, denies same.

17. The allegations set forth in Paragraph 17 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 17, and, therefore, denies same.

18. The allegations set forth in Paragraph 18 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 18, and, therefore, denies same.

19. The allegations set forth in Paragraph 19 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 19, and, therefore, denies same.

20. To the extent Paragraph 20 states legal conclusions, or contains allegations not directed at Merck, no response is required. To the extent Merck may be required to respond, Merck states that in 1982, certain AstraZeneca Defendants (and/or their predecessors) entered into agreements with Merck & Co., Inc. (now Merck Sharp & Dohme Corp.), and the agreements speak for themselves. Merck denies the remaining allegations set forth in Paragraph 20.

21. Merck denies the allegations set forth in Paragraph 21, but states that subsequent to entry into the agreements referenced in its response to Paragraph 20, certain AstraZeneca Defendants (and/or their predecessors) and/or Merck & Co., Inc. (now Merck Sharp & Dohme Corp.) developed omeprazole, later known as brand name Prilosec.

22. Merck admits that Prilosec® is an FDA-approved prescription medication and the conditions for which it is indicated are set forth in the product label. Merck denies the remaining allegations set forth in Paragraph 22 as stated.

23. The allegations set forth in Paragraph 23 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 23, and, therefore, denies same.

24. The allegations set forth in Paragraph 24 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 24, and, therefore, denies same.

25. The allegations set forth in Paragraph 25 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 25, and, therefore, denies same.

26. The allegations set forth in Paragraph 26 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 26, and, therefore, denies same.

27. The allegations set forth in Paragraph 27 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27, and, therefore, denies same.

28. The allegations set forth in Paragraph 28 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 28, and, therefore, denies same.

29. The allegations set forth in Paragraph 29 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 29, and, therefore, denies same.

30. The allegations set forth in Paragraph 30 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 30, and, therefore, denies same.

31. The allegations set forth in Paragraph 31 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 31, and, therefore, denies same.

32. The allegations set forth in Paragraph 32 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 32, and, therefore, denies same.

33. The allegations set forth in Paragraph 33 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 33, and, therefore, denies same.

34. The allegations set forth in Paragraph 34 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 34, and, therefore, denies same.

35. The allegations set forth in Paragraph 35 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 35, and, therefore, denies same.

36. The allegations set forth in Paragraph 36 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 36, and, therefore, denies same.

37. The allegations set forth in Paragraph 37 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 37, and, therefore, denies same.

38. The allegations set forth in Paragraph 38 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 38, and, therefore, denies same.

39. The allegations set forth in Paragraph 39 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 39, and, therefore, denies same.

40. The allegations set forth in Paragraph 40 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 40, and, therefore, denies same.

41. The allegations set forth in Paragraph 41 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 41, and, therefore, denies same.

42. The allegations set forth in Paragraph 42 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 42, and, therefore, denies same.

43. The allegations set forth in Paragraph 43 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 43, and, therefore, denies same.

44. The allegations set forth in Paragraph 44 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 44, and, therefore, denies same.

45. The allegations set forth in Paragraph 45 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 45, and, therefore, denies same.

46. The allegations set forth in Paragraph 46 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 46, and, therefore, denies same.

47. The allegations set forth in Paragraph 47 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 47, and, therefore, denies same.

48. The allegations set forth in Paragraph 48 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 48, and, therefore, denies same.

49. The allegations set forth in Paragraph 49 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 49, and, therefore, denies same.

50. The allegations set forth in Paragraph 50 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 50, and, therefore, denies same.

51. Merck & Co., Inc. denies that it is “d/b/a Merck, Sharp & Dohme Corporation” and further denies that “Merck & Co., Inc. d/b/a Merck, Sharp & Dohme Corporation” is a proper legal entity to be named as a defendant in this matter. By way of further response, the

entity formerly known as Merck & Co., Inc. is now named Merck Sharp & Dohme Corp., and that entity has had its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889 at all times relevant to this action. Merck Sharp & Dohme Corp. (herein referred to as “Merck”) denies all other allegations in Paragraph 51.

52. To the extent Paragraph 52 states legal conclusions, or contains allegations not directed at Merck, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 52.

53. To the extent Paragraph 53 states legal conclusions, or contains allegations not directed at Merck, no response is required. To the extent Merck may be required to respond, Merck states that for a period of time beginning in 1994, the entity known as Astra Merck Inc. sold certain products, including Prilosec. Merck denies the remaining allegations set forth in Paragraph 53.

54. To the extent that Paragraph 54 contains allegations not directed at Merck, no response is required. To the extent Merck may be required to respond, Merck states that the agreement referenced in Paragraph 20 speaks for itself. Merck otherwise denies any remaining allegations set forth in Paragraph 54 as stated.

55. To the extent Paragraph 55 states legal conclusions, or contains allegations not directed at Merck, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 55 as stated.

56. To the extent Paragraph 56 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 56 as stated.

57. To the extent Paragraph 57 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its responses to Paragraphs 20 and 53 and denies the remaining allegations set forth in Paragraph 57 as stated.

58. Merck admits that Prilosec® is an FDA-approved medication. Merck denies the remaining allegations set forth in Paragraph 58 as stated.

59. To the extent Paragraph 59 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 59 as stated.

60. To the extent Paragraph 60 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck incorporates by reference its response to Paragraphs 20 and 53 and denies the remaining allegations set forth in Paragraph 60 as stated.

61. To the extent Paragraph 61 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck admits that Nexium® is an FDA-approved medication, incorporates by reference its response to Paragraph 20 and denies the remaining allegations set forth in Paragraph 61 as stated.

62. Merck incorporates by reference its previous responses and denies the remaining allegations set forth in Paragraph 62 as stated.

63. Merck incorporates by reference its previous responses and denies the remaining allegations set forth in Paragraph 63 as stated.

64. Merck incorporates by reference its previous responses and denies the remaining allegations set forth in Paragraph 64 as stated.

65. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 65, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

66. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 66, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

67. The allegations set forth in Paragraph 67 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 67, and, therefore, denies same.

68. The allegations set forth in Paragraph 68 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 68, and, therefore, denies same.

69. The allegations set forth in Paragraph 69 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 69, and, therefore, denies same.

70. The allegations set forth in Paragraph 70 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 70, and, therefore, denies same.

71. The allegations set forth in Paragraph 71 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 71, and, therefore, denies same.

72. The allegations set forth in Paragraph 72 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 72, and, therefore, denies same.

73. The allegations set forth in Paragraph 73 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 73, and, therefore, denies same.

74. The allegations set forth in Paragraph 74 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 74, and, therefore, denies same.

75. The allegations set forth in Paragraph 75 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 75, and, therefore, denies same.

76. The allegations set forth in Paragraph 76 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 76, and, therefore, denies same.

77. The allegations set forth in Paragraph 77 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 77, and, therefore, denies same.

78. The allegations set forth in Paragraph 78 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 78, and, therefore, denies same.

79. The allegations set forth in Paragraph 79 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 79, and, therefore, denies same.

80. The allegations set forth in Paragraph 80 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 80, and, therefore, denies same.

81. The allegations set forth in Paragraph 81 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in

Paragraph 81, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

82. The allegations set forth in Paragraph 82 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 82, including the undefined, subjective term “substantial revenue,” and, therefore, denies same

83. The allegations set forth in Paragraph 83 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 83, and, therefore, denies same.

84. The allegations set forth in Paragraph 84 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 84, and, therefore, denies same.

85. The allegations set forth in Paragraph 85 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 85, and, therefore, denies same.

86. The allegations set forth in Paragraph 86 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 86, and, therefore, denies same.

87. The allegations set forth in Paragraph 87 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 87, and, therefore, denies same.

88. The allegations set forth in Paragraph 88 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 88, and, therefore, denies same.

89. The allegations set forth in Paragraph 89 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 89, and, therefore, denies same.

90. The allegations set forth in Paragraph 90 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 90, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

91. The allegations set forth in Paragraph 91 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 91, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

92. The allegations set forth in Paragraph 92 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 92, and, therefore, denies same.

93. The allegations set forth in Paragraph 93 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 93, and, therefore, denies same.

94. The allegations set forth in Paragraph 94 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 94, and, therefore, denies same.

95. The allegations set forth in Paragraph 95 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 95, and, therefore, denies same.

96. The allegations set forth in Paragraph 96 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 96, and, therefore, denies same.

97. The allegations set forth in Paragraph 97 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 97, and, therefore, denies same.

98. The allegations set forth in Paragraph 98 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 98, and, therefore, denies same.

99. The allegations set forth in Paragraph 99 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 99, and, therefore, denies same.

100. The allegations set forth in Paragraph 100 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 100, and, therefore, denies same.

101. The allegations set forth in Paragraph 101 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 101, and, therefore, denies same.

102. The allegations set forth in Paragraph 102 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 102, and, therefore, denies same.

103. The allegations set forth in Paragraph 103 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 103, and, therefore, denies same,

104. The allegations set forth in Paragraph 104 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 104, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

105. The allegations set forth in Paragraph 105 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 105, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

106. The allegations set forth in Paragraph 106 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 106, and, therefore, denies same.

107. The allegations set forth in Paragraph 107 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 107, and, therefore, denies same.

108. The allegations set forth in Paragraph 108 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 108, and, therefore, denies same.

109. The allegations set forth in Paragraph 109 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 109, and, therefore, denies same.

110. The allegations set forth in Paragraph 110 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 110, and, therefore, denies same.

111. The allegations set forth in Paragraph 111 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 111, and, therefore, denies same.

112. The allegations set forth in Paragraph 112 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 112, and, therefore, denies same.

113. The allegations set forth in Paragraph 113 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 113, and, therefore, denies same.

114. The allegations set forth in Paragraph 114 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 114, and, therefore, denies same.

115. The allegations set forth in Paragraph 115 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 115, and, therefore, denies same.

116. The allegations set forth in Paragraph 116 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 116, and, therefore, denies same.

117. The allegations set forth in Paragraph 117 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 117, and, therefore, denies same.

118. The allegations set forth in Paragraph 118 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 118, and, therefore, denies same.

119. The allegations set forth in Paragraph 119 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 119, and, therefore, denies same.

120. The allegations set forth in Paragraph 120 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 120, and, therefore, denies same.

121. The allegations set forth in Paragraph 121 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 121, and, therefore, denies same.

122. The allegations set forth in Paragraph 122 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

123. The allegations set forth in Paragraph 123 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 123, including the undefined, subjective term “substantial revenue,” and, therefore, denies same.

124. Merck denies the allegations set forth in Paragraph 124 as stated.

125. Merck denies the allegations set forth in Paragraph 125 as stated.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. Merck admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 126 as stated.

127. Merck admits that Nexium® and Prilosec® are proton pump inhibitor medications approved by the FDA and that their respective clinical pharmacologies are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 127 as stated.

128. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 128, including the undefined, subjective terms “most commercially successful,” top ten best-selling,” and “most dispensed,” and, therefore, denies same.

129. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 129, and, therefore, denies same.

130. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 130, and, therefore, denies same.

131. Merck admits that the document referenced in Paragraph 131 speaks for itself. Merck is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 131, and, therefore, denies same.

B. PPI Products Cause Severe Kidney Injuries

132. Merck admits that the document referenced in Paragraph 132 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 132 as stated.

133. Merck denies the allegations set forth in Paragraph 133 as stated.

i. PPI-Induced Acute Interstitial Nephritis ("AIN")

134. Merck admits that the documents referenced in Paragraph 134 speak for themselves. Merck otherwise denies the allegations set forth in Paragraph 134 as stated.

135. Merck admits that the document referenced in Paragraph 135 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 135 as stated.

136. Merck admits that the document referenced in Paragraph 136 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 136 as stated.

137. Merck admits that the document referenced in Paragraph 137 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 137 as stated.

138. Merck admits that the Public Citizen Petition to the FDA is dated August 23, 2011, and that it speaks for itself, but otherwise denies the allegations set forth in Paragraph 138 as stated.

139. Merck admits that the Public Citizen Petition speaks for itself, but otherwise denies the allegations set forth in Paragraph 139 as stated.

140. Merck admits that the FDA response to the Public Citizen Petition speaks for itself. Merck further admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its

obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 140 as stated.

141. Merck admits that the FDA response to the Public Citizen Petition speaks for itself, but otherwise denies the allegations set forth in Paragraph 141 as stated.

142. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 142 as stated.

143. The allegations set forth in Paragraph 143 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 143 regarding undefined “over-the-counter PPI Products” and “risk information,” and, therefore, denies same.

144. To the extent Paragraph 144 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies such allegations set forth in Paragraph 144 as stated. Merck denies the remaining allegations set forth in Paragraph 144.

145. The allegations set forth in Paragraph 145 are not directed at Merck, and therefore no response is required. To the extent Merck may be required to respond, Merck is without

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 145 regarding undefined “over-the-counter PPI Products” and, therefore, denies same.

146. To the extent Paragraph 146 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 146 as stated.

147. To the extent Paragraph 147 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 147 as stated.

148. Merck admits that the documents referenced in Paragraph 148 speak for themselves. Merck otherwise denies the allegations set forth in Paragraph 148, including all subparts, as stated.

149. To the extent Paragraph 149 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 149 as stated.

150. To the extent Paragraph 150 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 150 as stated.

151. To the extent Paragraph 151 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 151 as stated.

ii. PPI-Induced Acute Kidney Injury ("AKI")

152. To the extent Paragraph 152 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 152 as stated.

153. Merck is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 153, including the undefined term “studies” and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 153 as stated.

154. Merck is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 154, including the undefined term “studies” and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 154 as stated.

155. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 155 regarding undefined “prescription and over-the-counter” PPI Products, and, therefore, denies same.

156. To the extent Paragraph 156 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 156 as stated.

iii. PPI-Induced Chronic Kidney Disease ("CKD")

157. To the extent Paragraph 157 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 157 as stated.

158. To the extent Paragraph 158 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 158 as stated.

159. Merck admits that the document referenced in Paragraph 159 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 159 as stated.

160. Merck admits that the document referenced in Paragraph 160 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 160 as stated.

161. Merck admits that the document referenced in Paragraph 161 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 161 as stated.

162. To the extent Paragraph 162 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 162 as stated.

163. Merck admits that the document referenced in Paragraph 163 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 163 as stated.

164. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its

obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 164 as stated.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. To the extent Paragraph 165 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 165 as stated.

166. To the extent Paragraph 166 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 166 as stated.

167. Merck is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 167, including the undefined term “studies” and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 167 as stated.

168. To the extent Paragraph 168 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 168 as stated.

169. Merck denies the allegations set forth in Paragraph 169.

170. Merck denies the allegations set forth in Paragraph 170.

171. Merck is without knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 171, including the undefined term “studies” and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 171 as stated.

172. To the extent Paragraph 172 calls for a medical conclusion, any such response by Merck would be premature and inappropriate. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 172 as stated.

173. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 173 as stated.

D. Safer Alternatives to PPIs

174. To the extent Paragraph 174 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 174, including all subparts.

175. Merck admits that the document referenced in Paragraph 175 speaks for itself. Merck otherwise denies the allegations set forth in Paragraph 175 as stated.

176. To the extent Paragraph 176 states legal conclusions, no response is required. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 176.

E. Injuries Resulting from PPI Products

177. Merck denies the allegations set forth in Paragraph 177.

178. Merck denies the allegations set forth in Paragraph 178.

179. Merck denies the allegations set forth in Paragraph 179.

180. Merck denies the allegations set forth in Paragraph 180.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

181. Merck denies the allegations set forth in Paragraph 181.

182. Merck denies the allegations set forth in Paragraph 182.

183. Merck denies the allegations set forth in Paragraph 183.

184. Merck denies the allegations set forth in Paragraph 184.

185. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 185 regarding Plaintiff and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 185 and denies it breached any duty.

186. To the extent Paragraph 186 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies it breached any duty and denies the remaining allegations set forth in Paragraph 186 as stated.

187. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 187.

188. Merck denies the allegations set forth in Paragraph 188.

189. Merck denies the allegations set forth in Paragraph 189 as stated.

190. Merck denies the allegations set forth in Paragraph 190.

191. Merck denies the allegations set forth in Paragraph 191.

192. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the

Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 192.

193. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 193.

194. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 194.

195. To the extent Paragraph 195 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA, accompanied by FDA-approved package inserts, and that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and

transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 195.

G. Defendants Violations of Federal Law

196. Merck denies the allegations set forth in Paragraph 196.

197. Merck denies the allegations set forth in Paragraph 197, including all subparts, and denies it breached any duty.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. To the extent Paragraph 198 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 198 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

199. To the extent Paragraph 199 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 199 .

200. To the extent Paragraph 200 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 200.

201. To the extent Paragraph 201 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 201.

202. To the extent Paragraph 202 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 202.

203. To the extent Paragraph 203 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 203 and denies it breached any duty.

204. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation, if any, under the law to provide adequate warnings and instructions. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 204 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 204.

205. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 205 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 207.

206. To the extent Paragraph 206 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 206, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 206.

207. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 207 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 207.

208. To the extent Paragraph 208 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 208 and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 208.

209. To the extent Paragraph 209 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 209, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 209.

210. To the extent Paragraph 210 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 210, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 210.

211. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 211 as to the actions of others and including the undefined term “studies or information” and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 211.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY

212. To the extent Paragraph 212 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 212 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

213. Merck denies the allegations set forth in Paragraph 213.

214. Merck denies the allegations set forth in Paragraph 214.

215. Merck denies the allegations set forth in Paragraph 215 as stated.

216. To the extent Paragraph 216 states legal conclusions, no response is required. To the extent a response is required, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 216 and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 216 as stated.

217. Merck denies the allegations set forth in Paragraph 217.

218. Merck denies the allegations set forth in Paragraph 218.

219. Merck denies the allegations set forth in Paragraph 219.

220. Merck denies the allegations set forth in Paragraph 220.

221. Merck denies the allegations set forth in Paragraph 221 .

222. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 222, and, therefore, denies same.

223. Merck denies the allegations set forth in Paragraph 223.

224. To the extent Paragraph 224 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 224 as stated and denies it breached any duty.

225. Merck denies the allegations set forth in Paragraph 225.

226. Merck denies the allegations set forth in Paragraph 226.

227. Merck denies the allegations set forth in Paragraph 227.

228. Merck denies the allegations set forth in Paragraph 228.

229. Merck denies the allegations set forth in Paragraph 229.

230. Merck denies the allegations set forth in Paragraph 230.

231. Merck denies the allegations set forth in Paragraph 231.

232. Merck denies the allegations set forth in Paragraph 232.

233. Merck denies the allegations set forth in Paragraph 233.

234. Merck denies the allegations set forth in Paragraph 234.

235. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 235, and, therefore, denies same.

236. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 236, and, therefore, denies same.

237. Merck denies the allegations set forth in Paragraph 237, including all subparts.

238. Merck denies the allegations set forth in Paragraph 238.

239. Merck denies the allegations set forth in Paragraph 239.

240. Merck denies the allegations set forth in Paragraph 240.

241. Merck denies the allegations set forth in Paragraph 241.

242. Merck denies the allegations set forth in Paragraph 242.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 242. Merck also requests a trial by jury.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

243. To the extent Paragraph 243 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 243 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

244. Merck denies the allegations set forth in Paragraph 244.

245. Merck denies the allegations set forth in Paragraph 245.

246. Merck denies the allegations set forth in Paragraph 246.

247. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 247, and, therefore, denies same.

248. Merck denies the allegations set forth in Paragraph 248.

249. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 249, and, therefore, denies same.

250. Merck denies the allegations set forth in Paragraph 250

251. Merck denies the allegations set forth in Paragraph 251.

252. Merck denies the allegations set forth in Paragraph 252.

253. Merck denies the allegations set forth in Paragraph 253.

254. Merck denies the allegations set forth in Paragraph 254.

255. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 255 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 255.

256. Merck denies the allegations set forth in Paragraph 256.

257. Merck denies the allegations set forth in Paragraph 257.

258. Merck denies the allegations set forth in Paragraph 258.

259. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 259 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 259.

260. Merck denies the allegations set forth in Paragraph 260.

261. Merck denies the allegations set forth in Paragraph 261.

262. Merck denies the allegations set forth in Paragraph 262.

263. Merck denies the allegations set forth in Paragraph 263.

264. Merck denies the allegations set forth in Paragraph 264.

265. Merck denies the allegations set forth in Paragraph 265.

266. Merck denies the allegations set forth in Paragraph 266.

267. Merck denies the allegations set forth in Paragraph 267.

268. Merck denies the allegations set forth in Paragraph 268.

269. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 269 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 269.

270. Merck denies the allegations set forth in Paragraph 270.

271. Merck denies the allegations set forth in Paragraph 271.

272. Merck denies the allegations set forth in Paragraph 272.

273. Merck denies the allegations set forth in Paragraph 273.

274. Merck denies the allegations set forth in Paragraph 274.

275. Merck denies the allegations set forth in Paragraph 275.

276. Merck denies the allegations set forth in Paragraph 276.

277. Merck denies the allegations set forth in Paragraph 277.

278. Merck denies the allegations set forth in Paragraph 278.

279. Merck denies the allegations set forth in Paragraph 279.

280. Merck denies the allegations set forth in Paragraph 280.

281. Merck denies the allegations set forth in Paragraph 281.

282. Merck denies the allegations set forth in Paragraph 282.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 282. Merck also requests a trial by jury.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. To the extent Paragraph 283 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 283 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

284. Merck denies the allegations set forth in Paragraph 284.

285. Merck denies the allegations set forth in Paragraph 285.

286. To the extent Paragraph 286 states legal conclusions, no response is required. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 286 as stated and denies it breached any duty.

287. Merck denies the allegations set forth in Paragraph 287.

288. Merck denies the allegations set forth in Paragraph 288.

289. To the extent Paragraph 289 states legal conclusions, no response is required. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 289 as stated.

290. Merck denies the allegations set forth in Paragraph 290.

291. To the extent Paragraph 291 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 291 and denies it breached any duty.

292. Merck denies the allegations set forth in Paragraph 292.

293. Merck denies the allegations set forth in Paragraph 293.

294. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 294, and, therefore, denies same.

295. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 295 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 295.

296. To the extent Paragraph 296 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 296 as stated.

297. Merck denies the allegations set forth in Paragraph 297.

298. To the extent Paragraph 298 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 298, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 298.

299. To the extent Paragraph 299 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 299 and denies it breached any duty.

300. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 300 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 300.

301. Merck denies the allegations set forth in Paragraph 301.

302. To the extent Paragraph 302 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 302 and denies it breached any duty.

303. Merck admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels.

Merck denies the remaining allegations set forth in Paragraph 303.

304. Merck denies the allegations set forth in Paragraph 304.

305. Merck denies the allegations set forth in Paragraph 305.

306. To the extent Paragraph 306 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in

Paragraph 306, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 306.

307. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 307 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 307.

308. Merck denies the allegations set forth in Paragraph 308.

309. Merck denies the allegations set forth in Paragraph 309.

310. Merck denies the allegations set forth in Paragraph 310.

311. Merck denies the allegations set forth in Paragraph 311.

312. Merck denies the allegations set forth in Paragraph 312.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 312. Merck also requests a trial by jury.

COUNT IV **NEGLIGENCE**

313. To the extent Paragraph 313 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 313 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

314. To the extent Paragraph 314 states legal conclusions, no response is required. To the extent Merck is required to respond, Merck denies the allegations set forth in Paragraph 314 as stated and denies it breached any duty.

315. Merck denies the allegations set forth in Paragraph 315 and denies it breached any duty.

316. Merck denies the allegations set forth in Paragraph 316, including all subparts.

317. Merck denies the allegations set forth in Paragraph 317.

318. Merck denies the allegations set forth in Paragraph 318.

319. Merck denies the allegations set forth in Paragraph 319.

320. Merck denies the allegations set forth in Paragraph 320.

321. Merck denies the allegations set forth in Paragraph 321.

322. Merck denies the allegations set forth in Paragraph 322.

323. Merck admits that Nexium® and Prilosec® are FDA-approved medications and that the conditions for which each are indicated are set forth in the respective product labels.

Merck denies the remaining allegations set forth in Paragraph 323.

324. Merck denies the allegations set forth in Paragraph 324.

325. Merck denies the allegations set forth in Paragraph 325.

326. Merck denies the allegations set forth in Paragraph 326.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 326. Merck also requests a trial by jury.

COUNT V
NEGLIGENCE PER SE

327. To the extent Paragraph 327 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 327 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

328. Merck denies the allegations set forth in Paragraph 328.

329. To the extent Paragraph 329 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 329 as stated.

330. Merck denies the allegations set forth in Paragraph 330.

331. To the extent Paragraph 331 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 331 as stated.

332. To the extent Paragraph 332 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 332 as stated.

333. Merck denies the allegations set forth in Paragraph 333.

334. Merck denies the allegations set forth in Paragraph 334.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 334. Merck also requests a trial by jury.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. To the extent Paragraph 335 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 335 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

336. Merck denies the allegations set forth in Paragraph 336 as stated and denies it breached any duty.

337. Merck denies the allegations set forth in Paragraph 337.

338. Merck denies the allegations set forth in Paragraph 338.

339. Merck denies the allegations set forth in Paragraph 339.

340. Merck denies the allegations set forth in Paragraph 340.

341. Merck denies the allegations set forth in Paragraph 341.

342. Merck denies the allegations set forth in Paragraph 342.

343. To the extent Paragraph 343 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 343, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 343.

344. Merck denies the allegations set forth in Paragraph 344.

345. To the extent Paragraph 345 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 345.

346. Merck denies the allegations set forth in Paragraph 346.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 346. Merck also requests a trial by jury.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.72

347. To the extent Paragraph 347 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph

347 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

348. Merck denies the allegations set forth in Paragraph 348 as stated.

349. Merck denies the allegations set forth in Paragraph 349.

350. Merck denies the allegations set forth in Paragraph 350.

351. To the extent Paragraph 351 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 351, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 351.

352. Merck denies the allegations set forth in Paragraph 352.

353. Merck denies the allegations set forth in Paragraph 353.

354. Merck denies the allegations set forth in Paragraph 354.

355. Merck denies the allegations set forth in Paragraph 355.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 355. Merck also requests a trial by jury.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. To the extent Paragraph 356 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 356 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

357. To the extent Paragraph 357 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 357.

358. To the extent Paragraph 358 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 358.

359. To the extent Paragraph 359 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 359.

360. To the extent Paragraph 360 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and accompanied by FDA-approved package inserts, which speak for themselves. Merck further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® and Prilosec® package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. Merck fulfilled its obligation under the law to provide adequate warnings and instructions. Merck denies the remaining allegations set forth in Paragraph 360.

361. Merck denies the allegations set forth in Paragraph 361.

362. To the extent Paragraph 362 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 362, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 362.

363. Merck denies the allegations set forth in Paragraph 363.

364. Merck denies the allegations set forth in Paragraph 364, including all subparts.

365. Merck denies the allegations set forth in Paragraph 365.

366. To the extent Paragraph 366 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 366, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 366.

367. Merck denies the allegations set forth in Paragraph 367.

368. Merck denies the allegations set forth in Paragraph 368.

369. To the extent Paragraph 369 states legal conclusions, no response is required. To the extent Merck may be required to respond Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 369.

370. To the extent Paragraph 370 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 370, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 370.

371. To the extent Paragraph 371 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in

Paragraph 371, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 371.

372. Merck denies the allegations set forth in Paragraph 372.

373. Merck denies the allegations set forth in Paragraph 373.

374. Merck denies the allegations set forth in Paragraph 374.

375. Merck denies the allegations set forth in Paragraph 375.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 375. Merck also requests a trial by jury.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. To the extent Paragraph 376 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 376 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

377. To the extent Paragraph 377 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations in Paragraph 377.

378. To the extent Paragraph 378 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 378.

379. Merck denies the allegations set forth in Paragraph 379.

380. To the extent Paragraph 380 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in

Paragraph 380, and, therefore, denies same. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 380.

381. To the extent Paragraph 381 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 381, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 381.

382. Merck denies the allegations set forth in Paragraph 382.

383. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the allegations set forth in Paragraph 383.

384. Merck denies the allegations set forth in Paragraph 384.

385. To the extent Paragraph 385 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 385, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 385.

386. Merck denies the allegations set forth in Paragraph 386.

387. Merck denies the allegations set forth in Paragraph 387.

388. Merck denies the allegations set forth in Paragraph 388.

389. Merck denies the allegations set forth in Paragraph 389.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 389. Merck also requests a trial by jury.

COUNT X
NEGLIGENT MISREPRESENTATION

390. To the extent Paragraph 390 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 390 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

391. Merck denies the allegations set forth in Paragraph 391.

392. To the extent Paragraph 392 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 392 and denies that it breached any duty.

393. Merck denies the allegations set forth in Paragraph 393.

394. Merck denies the allegations set forth in Paragraph 394.

395. Merck denies the allegations set forth in Paragraph 395.

396. Merck denies the allegations set forth in Paragraph 396.

397. Merck denies the allegations set forth in Paragraph 397.

398. To the extent Paragraph 398 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 398, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 398.

399. Merck denies the allegations set forth in Paragraph 399.

400. Merck denies the allegations set forth in Paragraph 400.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 400. Merck also requests a trial by jury.

COUNT XI
FRAUD AND FRAUDULENT MISREPRESENTATION

401. To the extent Paragraph 401 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 401 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

402. Merck denies the allegations set forth in Paragraph 402.

403. Merck admits that Nexium® and Prilosec® are prescription medications approved by the FDA and that the conditions for which each are indicated are set forth in the respective product labels. Merck denies the remaining allegations set forth in Paragraph 403 as stated.

404. Merck denies the allegations set forth in Paragraph 404.

405. Merck denies the allegations set forth in Paragraph 405.

406. Merck denies the allegations set forth in Paragraph 406.

407. Merck denies the allegations set forth in Paragraph 407.

408. To the extent Paragraph 408 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 408, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 408.

409. To the extent Paragraph 409 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 409, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 409.

410. Merck denies the allegations set forth in Paragraph 410.

411. Merck denies the allegations set forth in Paragraph 411.

412. Merck denies the allegations set forth in Paragraph 412.

413. Merck denies the allegations set forth in Paragraph 413.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 413. Merck also requests a trial by jury.

COUNT XII
GROSS NEGLIGENCE

414. To the extent Paragraph 414 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 414 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

415. Merck denies the allegations set forth in Paragraph 415, including all subparts.

416. Merck admits that Plaintiff seeks damages, but denies Plaintiff is entitled to the relief sought. Merck denies the remaining allegations set forth in Paragraph 416.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 416. Merck also requests a trial by jury.

COUNT XIII
FRAUDULENT CONCEALMENT

417. To the extent Paragraph 417 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 417 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

418. Merck denies the allegations set forth in Paragraph 418.

419. Merck denies the allegations set forth in Paragraph 419.

420. Merck denies the allegations set forth in Paragraph 420.

421. To the extent Paragraph 421 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 421, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 421.

422. Merck denies the allegations set forth in Paragraph 422.

423. To the extent Paragraph 423 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 423, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 423.

424. Merck denies the allegations set forth in Paragraph 424.

425. To the extent Paragraph 425 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 425 as stated and denies it breached any duty.

426. To the extent Paragraph 426 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 426 as stated and denies it breached any duty.

427. To the extent Paragraph 427 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 427 and denies it breached any duty.

428. To the extent Paragraph 428 states legal conclusions, no response is required. To the extent Merck may be required to respond, as to the actions of others, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 428, and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 428.

429. Merck denies the allegations set forth in Paragraph 429.

430. Merck denies the allegations set forth in Paragraph 430.

431. Merck denies the allegations set forth in Paragraph 431.

432. Merck denies the allegations set forth in Paragraph 432.

433. Merck denies the allegations set forth in Paragraph 433.

434. Merck denies the allegations set forth in Paragraph 434.

435. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 435 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 435.

436. Merck denies the allegations set forth in Paragraph 436.

437. Merck denies the allegations set forth in Paragraph 437.

438. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 438 as to the actions of others and, therefore, denies same. Merck denies the remaining allegations set forth in Paragraph 438.

439. Merck denies the allegations set forth in Paragraph 439.

440. Merck denies the allegations set forth in Paragraph 440.

441. Merck denies the allegations set forth in Paragraph 441.

Merck denies the allegations set forth in the unnumbered Paragraph immediately following Paragraph 441 and denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" Paragraph immediately following. Merck also requests a trial by jury.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. To the extent Paragraph 442 states legal conclusions, no response is required. To the extent Merck may be required to respond, Merck denies the allegations set forth in Paragraph 442 and re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

443. Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of "PPI Products" and, therefore denies same. Merck denies the remaining allegations set forth in Paragraph 443.

444. Merck denies the allegations set forth in Paragraph 444.

445. Merck denies the allegations set forth in Paragraph 445.

446. Merck denies the allegations set forth in Paragraph 446.

Merck denies that Plaintiff is entitled to any of the relief requested in the “WHEREFORE” Paragraph immediately following Paragraph 446. Merck also requests a trial by jury.

RESPONSE TO PRAYER FOR RELIEF

In response to the Paragraph entitled “Prayer for Relief,” Merck denies that Plaintiff is entitled to any of the relief requested.

DEFENSES

Discovery and investigation may reveal that one or more of the following defenses should be available to Merck in this matter. Merck accordingly preserves the right to assert these separate defenses. Upon completion of discovery, if facts warrant, Merck may withdraw any of these defenses as may be appropriate. Merck further reserves the right to amend this Answer to assert additional defenses and other claims as discovery proceeds.

By alleging the matters set forth below, Merck does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, nothing stated herein is intended or shall be construed as an acknowledgment that any particular issue or subject necessarily is relevant to Plaintiff’s allegations.

If necessary and/or in the alternative, Merck raises the following defenses available in Ohio or in any other State or Commonwealth of the United States, under statute or common law (hereinafter “state”), whose laws might be deemed controlling in this case, but reserves the right to amend its Answer to raise any additional defenses which it may have against Plaintiff’s claims:

1. Plaintiff’s claims and causes of action are barred by the applicable statute(s) of limitation, the applicable statute(s) of repose, and/or may be otherwise untimely.

2. Plaintiff fails to state a claim upon which relief can be granted as required by Ohio Rule of Civil Procedure 12(B).

3. This Court lacks personal jurisdiction over Merck with respect to Plaintiff's claims, and thus the Complaint should be dismissed under Rule 12(B)(2) of the Civil Rules.

4. Plaintiff fails to plead claims against Merck with sufficient particularity as required by Civil Rule 9(B).

5. Nexium® and Prilosec® are pharmaceuticals which were available only upon prescription of a licensed physician. Any warnings that Merck gave were transmitted to prescribing physicians and/or healthcare providers. Under Ohio or other applicable state law, Merck fulfilled its obligation to provide adequate warnings and instructions and Plaintiff's claims are therefore barred pursuant to the learned intermediary doctrine.

6. If Plaintiff sustained the injuries or damages as alleged, said injuries and expenses were directly and proximately caused by the acts and omissions (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more parties other than Merck over whom Merck had no supervision or control and for whose actions and omissions Merck has no legal responsibility. Merck is not liable for negligence and violated no duty that may have been owed to Plaintiff.

7. Merck's activities conformed to all state and federal statutes, regulations, and industry standards based upon the state of the knowledge that existed at the time.

8. Plaintiff's recovery is barred and/or should be reduced under the applicable law because of Plaintiff's comparative negligence or fault, culpable conduct, intentional acts, assumption of risk, and/or want of care.

9. Plaintiff's injuries and damages, if any, resulted from an intervening or superseding cause or causes and any act or omission on the part of Merck was not the proximate and/or competent producing cause of such alleged injuries or damages.

10. Merck did not sell or distribute products directly to Plaintiff. Plaintiff's claims are, therefore, barred by lack of privity between Plaintiff and Merck.

11. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards and techniques utilized with respect to the design, manufacture, marketing, distribution, and sale of Nexium® and Prilosec®, including adequate warnings and instructions with respect to the products' use included in the product's package inserts and other literature conformed to the applicable state of the art. The products in question, including their FDA-approved labeling, complied with the state of scientific and medical knowledge available to Merck at the time of its manufacture, distribution, and sale.

12. With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

13. Plaintiff's claims are barred in whole or in part under comment *k* to Section 402A of the Restatement (Second) of Torts.

14. Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of the products at issue and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment *j* to Section 402A of the Restatement (Second) of Torts.

15. Plaintiff's claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment *f* to Section 6, of the Restatement (Third) of Torts: Products Liability.

16. With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments *j* and *k* to Section 402A of the Restatement (Second) of Torts relegate Plaintiff's claims to a negligence cause of action.

17. Nexium® and Prilosec® complied with all applicable state and federal statutes regarding the products in question, including product safety regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged in by the Complaint. The products at issue were reasonably fit, suitable, and safe for their respective intended uses, demonstrating that due care was exercised with respect to the design, manufacture, testing, marketing, distribution, and sale of Nexium® and Prilosec®. In the event that Plaintiff's claims are not barred, Merck is entitled to a presumption that the products in question are free from any defect or defective condition as the plans or design for the products or the methods and techniques of manufacturing, inspecting, and testing the products were in conformity with government standards established for the drug industry that were in existence at the time the plans or designs for the products or the methods and techniques of manufacturing, inspecting, and testing the products were adopted.

18. Plaintiff's claims are barred because Nexium® and Prilosec® were neither defective nor unreasonably dangerous in their design, manufacture, distribution, or marketing, and were reasonably safe and reasonably fit for their intended use, thereby barring Plaintiff's recovery.

19. If Plaintiff sustained the injuries or damages as alleged, said injuries or damages were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of

the prescription drugs Nexium® and/or Prilosec® thereby barring Plaintiff's recovery against Merck.

20. Plaintiff's claims are barred to the extent Plaintiff knew the condition of Nexium® and/or Prilosec®, appreciated the risks of injury flowing from Nexium® and/or Prilosec® use, and nevertheless proceeded to use Nexium® and/or Prilosec® without regard to the danger of such risks. As a result, Plaintiff gave informed consent and/or assumed the risk of injury of which they now complain.

21. The extent of any risk associated with the use of the products at issue, the existence of which is not admitted, was, at the time of the distribution of said products by Merck, unknown and could not have been known by the use of ordinary care.

22. The public interest in the benefit and availability of the products which are the subject matter of this action precludes liability, if any, resulting from any activities undertaken by Merck, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there exists a risk inherent in the subject products, then such risk, if any, is outweighed by the benefit of the products.

23. Plaintiff's failure to warn claim is barred given that Merck had no duty to warn of risks of which they neither knew nor should have known at the time Nexium® and Prilosec® were designed, distributed, and manufactured.

24. Plaintiff's injuries and damages, if any, were the result of an idiosyncratic reaction that Merck could not have reasonably foreseen, thereby barring Plaintiff's recovery.

25. Plaintiff's claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or

contemporaneous) unrelated to any conduct of Merck or condition of the products, Nexium® and Prilosec®, thereby barring Plaintiff's recovery.

26. Plaintiff has not sustained an ascertainable loss of property or money, nor any actual injury or damages.

27. Plaintiff's claims are barred under the doctrine of economic loss.

28. Plaintiff failed to mitigate damages.

29. To the extent applicable, Plaintiff's breach of warranty claims are barred because there is no privity of contract between Plaintiff and Merck; Plaintiff failed to provide Merck with reasonable or adequate notice of the alleged breach of any such purported warranty pursuant to the applicable Uniform Commercial Code; Plaintiff did not reasonably rely upon such purported warranty; Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such purported warranty; and/or the purported warranty was appropriately disclaimed, excluded, or modified.

30. Merck's advertisements and labeling with respect to the products which are the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution and applicable state law.

31. Merck is entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

32. Merck denies any liability, but if Merck is ultimately found liable to Plaintiff, then it shall only be liable for their equitable share of Plaintiff's recovery since any liability which would be found against Merck will be insufficient to impose joint liability.

33. If Plaintiff recovers from Merck, Merck is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiff's alleged damages.

34. Any verdict or judgment rendered against Merck must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part, for any past or future claimed economic loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

35. Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences.

36. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be precluded or reduced accordingly.

37. To the extent Plaintiff seeks recovery of punitive or exemplary damages against Merck, unless Merck's liability for punitive damages and the appropriate amount of punitive damages is required to be established by clear and convincing evidence, any award of punitive damages would violate Merck's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the United States Constitution and under any applicable state constitution, and would be improper under the common law, public policies, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

38. To the extent Plaintiff seeks recovery of punitive or exemplary damages against Merck, any such claim of Plaintiff for punitive damages against Merck cannot be maintained

because there was no act or omission by Merck that was oppressive, fraudulent, or malicious. Additionally, any award of punitive damages under the applicable law would be unlawful and unauthorized, and would be void for vagueness, both facially and as applied, as a result of, among other deficiencies, the absence of adequate notice of what conduct is subject to punishment; the absence of adequate notice of what punishment may be imposed; and the absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that a jury may impose, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, under any applicable state constitution, and the common law and public policies of any applicable state.

39. To the extent Plaintiff seeks recovery of punitive damages against Merck, any such claim of Plaintiff for punitive damages against Merck cannot be maintained because any award of punitive damages under the applicable law would be by a jury that (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including residence, wealth, and corporate status of Merck, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is permitted to award punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award punitive damages in an amount that is not

both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any, (7) is not subject to adequate, independent, de novo trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards and in conformity with the United States Constitution as amended or any applicable state constitution. Any such verdict would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process and equal protection provisions of any applicable state constitution, and would be improper under the common law and public policies of that state.

40. Additionally, punitive damages may not be recovered to the extent such damages are: (1) imposed where state law is impermissibly vague, imprecise, or inconsistent, (2) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, or (3) imposed on the basis of anything other than Merck's conduct within the applicable state, or in any other way subjecting Merck to impermissible multiple punishment for the same alleged wrong.

41. To the extent Plaintiff seeks recovery of punitive or exemplary damages against Merck, any award of punitive damages based on anything other than Merck's conduct in connection with the design, manufacture, and sale of Nexium® and Prilosec® would violate the due process clause of the Fourteenth Amendment of the United States Constitution and the due process provisions of the Ohio state constitution, and would be improper under the common law and public policies of that state, because any other judgment for punitive damages in this case cannot protect Merck against impermissible punishment for the same wrong and against punishment for extraterritorial conduct, including conduct that is lawful in states other than the

applicable state. In addition, any award would violate principles of comity under the laws of that state.

42. Merck incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny.

43. Merck assert the provisions of all applicable statutory caps on damages of any sort, including compensatory, punitive, non-economic or exemplary damages, under all applicable regulations and/or laws.

44. There was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff or reduced the alleged risk, without substantially impairing the usefulness, safety, efficacy, or intended purpose of Nexium® and Prilosec®, thereby barring Plaintiff's recovery.

45. Plaintiff's purported allegations of misrepresentation fail to state a claim for which relief may be granted. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

46. The Merck products at issue have been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and regulations promulgated

thereunder. Therefore, Plaintiff's claims predicated on state tort law and alleging that Nexium® and/or Prilosec® are unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

47. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

48. Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating drugs, including the product at issue, and is specifically charged with determining the content of warnings and labeling for drugs.

49. Plaintiff's claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

50. Merck denies that Nexium® and/or Prilosec® were or are unreasonably dangerous or defective, not fit for its intended, ordinary purpose, or that such products created any liability under Ohio state law.

51. Loss of consortium claims must fail to the extent the allegedly injured spouse's claims fail, as such claims are derivative.

52. No act or omission by Merck was the proximate cause, contributing cause, or otherwise a cause of any damages alleged by Plaintiff. The negligence of other persons or entities who are not parties to this suit was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipate that more specific information

regarding the identity and potential liability of these non-parties will be developed during discovery.

53. To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Merck's rights under the United States Constitution.

54. Plaintiff received all or substantially all of the benefit from the subject products that Plaintiff hoped and intended to receive, and to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Merck must be correspondingly barred or reduced.

55. Plaintiff's claims are barred by laches, waiver, accord and satisfaction, payment, release, res judicata, estoppel, spoliation of evidence, statutory and regulatory compliance, and/or the applicability of arbitration and award.

56. Plaintiff's claims may be subject to dismissal or stay on the grounds of *forum non conveniens*.

57. Plaintiff is not entitled to recover attorneys' fees under any applicable law.

58. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to assert them.

59. If Plaintiff was injured by Nexium® and/or Prilosec®, those injuries occurred because the product(s) was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and in disregard of instructions and directions regarding its use. Such misuse was not reasonably foreseeable to Merck.

60. Merck denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of Merck, or at the

instruction or subject to the control of Merck with regard to any of the actions described in the Complaint; thus, Merck is not liable for any acts or omissions of such third parties as a matter of law.

61. Merck avers that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

62. Plaintiff's claims are barred, in whole or in part, because Merck's advertisements and labeling with respect to Nexium® and Prilosec® were not false or misleading and, therefore, constitute protected commercial speech under the First Amendment of the United States Constitution and Section 11, Article I of the Ohio Constitution.

63. If Plaintiff sustained the injuries or incurred the expenses alleged, they may have been caused, in whole or in part, by operation of nature or by an act of God or other intervening causes.

64. No act or omission of Merck was malicious, willful, wanton, reckless, grossly negligent or intentional and, therefore, any award of punitive damages is barred.

65. Merck incorporates by reference each defense asserted by any other Defendant.

66. Merck is entitled to all protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in each case.

67. Merck hereby raises and preserves the defense of improper venue.

68. Plaintiff fails to state a claim to the extent that Defendants did not manufacture or distribute the product allegedly ingested by Plaintiff.

69. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code 2307.71 through 2307.81, and Merck hereby asserts all allowable limitations and defenses under the Ohio Products Liability Act.

70. Merck hereby pleads all available defenses and principles as set forth in Ohio Rev. Code 2307.22-2307.29.

71. Plaintiff's claims are barred because Nexium® and Prilosec® are "ethical drugs" as defined by Ohio Rev. Code 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.

72. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in O.R.C. 2315.22, *et seq.* and 2315.32-2315.36.

73. Plaintiff's recovery as against Merck should be barred in accordance with Ohio Rev. Code 2307.78.

74. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code 2315.18 and 2315.21.

75. Plaintiff's right to recover damages, if any, is statutorily limited by Ohio's wrongful death statute, Ohio Rev. Code 2125.01 through 2125.04.

76. Plaintiff's claims for punitive or exemplary damages as set forth in the complaint are barred by Ohio Rev. Code 2307.80(C).

77. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code 2307.71 through 2307.81.

78. Ohio's Consumer Sales Practices Act, Ohio Rev. Code 1345.12(C), specifically precludes claims for personal injury or death.

79. Plaintiff fails to state a claim for relief under Ohio Rev. Code 1345.01, *et seq.*

80. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in

violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

81. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

82. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code 2307.711.

83. All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct Merck had no reason to anticipate and for whose conduct Merck is not and were not responsible. Ohio Revised Code 2307.22, *et seq.*

84. The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code 2307.23.

85. One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Rev. Code 2307.71 through 2307.80, 2315.18, 2315.21, *et al.*

86. Plaintiff's design defect claims fail under Ohio Rev. Code 2307.75(D) because adequate warning and instruction were provided under Ohio Rev. Code 2307.76 concerning any unavoidably unsafe aspects of the product.

87. Plaintiff's design defect claims fail under Ohio Rev. Code 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

88. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Rev. Code 2307.75(F).

89. Plaintiff's inadequate warning claims are barred under Ohio Rev. Code 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

WHEREFORE, Merck demands judgment in its favor and against Plaintiff, dismissing the Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and further relief as the Court deems just and necessary.

Respectfully submitted,

ICE MILLER LLP

/s/ Daniel M. Anderson

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Pharmaceuticals LP, AstraZeneca LP and Merck

Sharp & Dohme Corporation

JURY DEMAND

Merck hereby demands a jury trial on all claims so triable in this action.

/s/ Daniel M. Anderson

Daniel M. Anderson

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was filed electronically on August 2, 2019, and a true and accurate copy was served via electronic mail the same day upon the attached Master Service List.

/s/ Daniel M. Anderson

Ohio PPI Cases Master Service List

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IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA A. BEHYMER

Plaintiff,

V.

ABBOTT LABORATORIES, et al.

Defendants.

CASE NO. A 1902638

JUDGE SYLVIA S. HENDON

NOTICE OF APPEARANCE

Please take notice that Jennifer L. Steinmetz (Ohio Attorney Registration No. 0088589) of the law firm of Tucker Ellis LLP, 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113, hereby enters her appearance on behalf of Defendants Abbott Laboratories, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., Takeda Development Center Americas, Inc., and Takeda Pharmaceutical Company Limited. Ms. Steinmetz appears along with Tariq M. Naeem, also of the law firm of Tucker Ellis LLP.

/s/ Jennifer L. Steinmetz

Tariq M. Naeem (0072808)

Jennifer L. Steinmetz (0088589)

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*Attorney for Defendants Abbott Laboratories,
Takeda Pharmaceuticals U.S.A., Inc., Takeda
Pharmaceuticals America, Inc., Takeda
Development Center Americas, Inc., and Takeda
Pharmaceutical Company Limited*



PROOF OF SERVICE

I hereby certify that on August 2, 2019, foregoing **Notice of Appearance** was filed electronically and that a copy has been served upon counsel of record by the court's electronic filing system.

/s/ Jennifer L. Steinmetz

Jennifer L. Steinmetz (0088589)

*Attorney for Defendants Abbott Laboratories,
Takeda Pharmaceuticals U.S.A., Inc., Takeda
Pharmaceuticals America, Inc., Takeda
Development Center Americas, Inc., and Takeda
Pharmaceutical Company Limited*

**IN COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A. BEHYMER,

CASE NO. A 1902638

Plaintiff,

JURY DEMAND ENDORSED HEREON

vs.

ABBOTT LABORATORIES, et al.,

Judge Charles J. Kubicki, Jr.

Defendants.

**DEFENDANTS NOVARTIS CORPORATION, NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.,
AND NOVARTIS VACCINES AND DIAGNOSTICS, INC., ANSWER TO
PLAINTIFF'S COMPLAINT**

Defendants Novartis Corporation¹ (“Novartis Corp.”), Novartis Pharmaceuticals Corporation (“NPC”), Novartis Institutes for Biomedical Research, Inc. (“NIBRI”), and Novartis Vaccines and Diagnostics, Inc. (“NV&D”), collectively “Defendants,” respond to Plaintiff’s Complaint (“the Complaint”) as follows²:

With respect to the introductory paragraph preceding Paragraph 1 of the Complaint, Defendants Novartis Corp., NPC, NIBRI, and NV&D admit that their names are Novartis Corporation, Novartis Pharmaceuticals Corporation, Novartis Institutes for Biomedical Research,

¹ Plaintiff’s Complaint incorrectly names “Novartis Corporation, Lichstrasse 35, CH-4056 Basel, Switzerland” in the case caption. To the extent plaintiff intended to name Novartis AG, which is located in Basel, Switzerland, Novartis AG joins in this answer. However, Novartis AG does not waive, and expressly reserves, all venue, service, and jurisdictional defenses, including improper venue, *forum non conveniens*, lack of personal jurisdiction, lack of subject matter jurisdiction, insufficient process, and insufficient service of process.

² Except as otherwise expressly set forth below, Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations refer or relate to any other defendant, person or entity. Defendants respond only on their own behalf and not on the behalf of any other entity.



Inc., and Novartis Vaccines & Diagnostics, Inc. The remaining allegations contained in the introductory paragraph concern parties other than Defendants and thus no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

NATURE OF THE ACTION

1. Defendants deny that Plaintiff is entitled to any of the relief sought and specifically denies that Defendants' drugs caused Plaintiff any injuries or damages. To the extent the remaining allegations contained in Paragraph 1 are addressed to parties other than Defendants, no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

2. Paragraph 2 of the Complaint does not contain any allegations, and thus no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

3. To the extent the allegations in Paragraph 3 of the Complaint are directed to Defendants, Defendants deny the allegations. To the extent the remaining allegations are addressed to parties other than Defendants, no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

4. Defendants state that the terms "affiliates," "subsidiaries," "alter-egos," and "joint-venturers" are legal terms of art and the legal conclusions contained therein do not require an answer. Defendants also do not know what is meant by the phrase "responsible for," as that phrase is vague and ambiguous and are unable to respond to the allegations in Paragraph 4 of the

Complaint on this basis as well. Answering further, Defendants deny that they are responsible for the design, research, development, testing, manufacture, packaging, labeling, marketing, promotion, distribution, and/or selling any of the products identified in Paragraph 4. To the extent the remaining allegations in Paragraph 4 of the Complaint are directed to Defendants, Defendants deny the same. To the extent the allegations in Paragraph 4 of the Complaint are addressed to parties other than Defendants, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

5. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations asserted in Paragraph 5 of the Complaint and therefore deny the same.

PARTIES, JURISDICTION & VENUE

6. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations asserted in Paragraph 6 of the Complaint and therefore deny the same.

I. PLAINTIFF

7. The allegations in Paragraph 7 and sub-parts (a) and (b) of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 7 and sub-parts (a) and (b) of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 7 and sub-parts (a) and (b) of the Complaint are directed to Defendants, Defendants deny that they caused plaintiff any injuries. Defendants deny all remaining allegations in Paragraph 7 and sub-parts (a) and (b) of the Complaint.

II. DEFENDANTS

8. The allegations in Paragraph 8 of the Complaint are addressed to parties other than Defendants to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

9. The allegations in Paragraph 9 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

10. The allegations in Paragraph 10 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

11. The allegations in Paragraph 11 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

12. The allegations in Paragraph 12 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

13. The allegations in Paragraph 13 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

14. The allegations in Paragraph 14 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

15. The allegations in Paragraph 15 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

16. The allegations in Paragraph 16 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

17. The allegations in Paragraph 17 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

18. The allegations in Paragraph 18 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

19. The allegations in Paragraph 19 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

20. The allegations in Paragraph 20 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

21. The allegations in Paragraph 21 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

22. The allegations in Paragraph 22 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

23. The allegations in Paragraph 23 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

24. The allegations in Paragraph 24 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

25. The allegations in Paragraph 25 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

26. The allegations in Paragraph 26 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

27. The allegations in Paragraph 27 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

28. The allegations in Paragraph 28 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

29. The allegations in Paragraph 29 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

30. The allegations in Paragraph 30 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

31. The allegations in Paragraph 31 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

32. The allegations in Paragraph 32 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

33. The allegations in Paragraph 33 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

34. The allegations in Paragraph 34 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

35. The allegations in Paragraph 35 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

36. The allegations in Paragraph 36 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

37. The allegations in Paragraph 37 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

38. The allegations in Paragraph 38 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

39. The allegations in Paragraph 39 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

40. The allegations in Paragraph 40 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

41. The allegations in Paragraph 41 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

42. The allegations in Paragraph 42 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

43. The allegations in Paragraph 43 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same. To the extent that the allegations in Paragraph 43 of the Complaint refer to an agreement not attached to or part of this Complaint, Defendants state that this agreement speaks for itself. Defendants deny the allegations in Paragraph 43 to the extent they misstate or mischaracterize the agreement.

44. The allegations in Paragraph 44 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

45. The allegations in Paragraph 45 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

46. The allegations in Paragraph 46 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

47. The allegations in Paragraph 47 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

48. The allegations in Paragraph 48 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

49. The allegations in Paragraph 49 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

50. The allegations in Paragraph 50 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

51. The allegations in Paragraph 51 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

52. The allegations in Paragraph 52 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

53. The allegations in Paragraph 53 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

54. The allegations in Paragraph 54 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

55. The allegations in Paragraph 55 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

56. The allegations in Paragraph 56 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

57. The allegations in Paragraph 57 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

58. The allegations in Paragraph 58 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

59. The allegations in Paragraph 59 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

60. The allegations in Paragraph 60 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

61. The allegations in Paragraph 61 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

62. The allegations in Paragraph 62 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

63. The allegations in Paragraph 63 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

64. The allegations in Paragraph 64 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

65. The allegations in Paragraph 65 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

66. The allegations in Paragraph 66 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

67. Defendants admit the allegations in Paragraph 67 of the Complaint.

68. Defendants admit the allegations in Paragraph 68 of the Complaint.

69. Defendants admit the allegations in Paragraph 69 of the Complaint.

70. Defendants admit the allegations in Paragraph 70 of the Complaint

71. Defendants deny the allegations in Paragraph 71 of the Complaint.

72. The allegations in Paragraph 72 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 72 of the Complaint.

73. Paragraph 73 of the Complaint contains no allegations and thus no response is required.

74. The allegations in Paragraph 74 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 74 of the Complaint.

75. The allegations in Paragraph 75 of the Complaint constitute legal conclusions to which no response is required. Answering further, Defendants state that Paragraph 75 refers to an agreement not attached to or part of this Complaint, and Defendants state that this agreement speaks for itself. Defendants deny the allegations in Paragraph 75 to the extent they misstate or mischaracterize the agreement.

76. Defendants do not know what is meant by the phrases “[a]s a part of their business,” “at all relevant times,” and “involved in,” as those phrases are vague and ambiguous. Defendants thus are unable to respond to the allegations in Paragraph 76 of the Complaint and on that ground deny such allegations.

77. Defendants deny the allegations in Paragraph 77 of the Complaint.

78. Defendants deny the allegations in Paragraph 78 of the Complaint.

79. Defendants deny the allegations in Paragraph 79 of the Complaint.

80. Defendants deny the allegations in Paragraph 80 of the Complaint.

81. Defendants state that the term “substantial revenue” is a legal term of art and the legal conclusions therein do not require an answer. Answering further, Defendants do not know

what is meant by the term “substantial,” as this term is vague and ambiguous. Defendants thus are unable to respond to the allegations in Paragraph 81 and on that ground deny such allegations.

82. Defendants state that the terms “expected,” “substantial revenue,” and “interstate commerce” are legal terms of art and the legal conclusions therein do not require an answer. Defendants also do not know what is meant by the terms “acts,” “consequence,” and “substantial,” as these words are vague and ambiguous and Defendants are unable to respond to the allegations in Paragraph 82 of the Complaint and on that ground deny such allegations.

83. The allegations in Paragraph 83 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

84. The allegations in Paragraph 84 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

85. The allegations in Paragraph 85 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

86. The allegations in Paragraph 86 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

87. The allegations in Paragraph 87 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

88. The allegations in Paragraph 88 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

89. The allegations in Paragraph 89 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

90. The allegations in Paragraph 90 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

91. The allegations in Paragraph 91 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

92. The allegations in Paragraph 92 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

93. The allegations in Paragraph 93 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

94. The allegations in Paragraph 94 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

95. The allegations in Paragraph 95 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

96. The allegations in Paragraph 96 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

97. The allegations in Paragraph 97 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

98. The allegations in Paragraph 98 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

99. The allegations in Paragraph 99 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

100. The allegations in Paragraph 100 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

101. The allegations in Paragraph 101 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

102. The allegations in Paragraph 102 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

103. The allegations in Paragraph 103 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

104. The allegations in Paragraph 104 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

105. The allegations in Paragraph 105 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

106. The allegations in Paragraph 106 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

107. The allegations in Paragraph 107 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

108. The allegations in Paragraph 108 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

109. The allegations in Paragraph 109 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

110. The allegations in Paragraph 110 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

111. The allegations in Paragraph 111 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

112. The allegations in Paragraph 112 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

113. The allegations in Paragraph 113 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

114. The allegations in Paragraph 114 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

115. The allegations in Paragraph 115 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

116. The allegations in Paragraph 116 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

117. The allegations in Paragraph 117 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

118. The allegations in Paragraph 118 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

119. The allegations in Paragraph 119 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required,

Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

120. The allegations in Paragraph 120 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

121. The allegations in Paragraph 121 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

122. The allegations in Paragraph 122 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

123. The allegations in Paragraph 123 of the Complaint are addressed to parties other than Defendants, to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

124. The allegations in Paragraph 124 of the Complaint contain legal conclusions, to which no response is required. To the extent the allegations in Paragraph 124 of the Complaint are directed to Defendants, Defendants deny the allegations. To the extent the remaining allegations are addressed to parties other than Defendants, no response is required. To the extent

a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

125. The allegations in Paragraph 125 of the Complaint contain legal conclusions, to which no response is required. To the extent the allegations in Paragraph 125 of the Complaint are directed to Defendants, Defendants deny the allegations. To the extent the remaining allegations are addressed to parties other than Defendants, no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of such allegations and therefore deny the same.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

126. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 126 of the Complaint and therefore deny the same.

127. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 127 of the Complaint and therefore deny the same.

128. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 128, including the undefined, subjective terms “most commercially successful,” “top ten best-selling,” and “most dispensed,” and, therefore, deny same.

129. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 129 of the Complaint and therefore deny the same.

130. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 130 of the Complaint and therefore deny the same.

131. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 131 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

B. PPI Products Cause Severe Kidney Injuries

132. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 132 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

133. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 133 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

i. PPI-Induced Acute Interstitial Nephritis

134. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 134 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

135. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 135 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

136. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 136 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

137. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 137 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

138. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 138 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

139. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 139 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this

Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

140. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 140 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

141. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 141 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

142. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 142 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

143. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 143 of the Complaint and therefore deny the same.

Moreover, to the extent the allegations in Paragraph 143 of the Complaint are addressed to parties other than Defendants, no response is required. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such

documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

144. The allegations in Paragraph 144 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 144 of the Complaint and therefore deny the same. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

145. The allegations in Paragraph 145 of the Complaint state legal conclusions to which no response is required. Moreover, to the extent the allegations in Paragraph 145 of the Complaint are addressed to parties other than Defendants, no response is required. To the extent the allegations in Paragraph 145 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 145 of the Complaint.

146. To the extent the allegations in Paragraph 146 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 146 of the Complaint and therefore deny the same.

147. To the extent the allegations in Paragraph 147 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information

to form a belief as to the truth of the allegations in Paragraph 147 of the Complaint and therefore deny the same.

148. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 148 and sub-parts (a) and (b) of the Complaint and therefore deny the same. Answering further, these allegations refer to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

149. To the extent the allegations in Paragraph 149 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 149 of the Complaint and therefore deny the same.

150. To the extent the allegations in Paragraph 150 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 150 of the Complaint and therefore deny the same.

151. To the extent the allegations in Paragraph 151 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 151 of the Complaint and therefore deny the same.

ii. PPI-Induced Acute Kidney Injury (“AKI”)

152. To the extent the allegations in Paragraph 152 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 152 of the Complaint and therefore deny the same.

153. The allegations in Paragraph 153 of the Complaint refer to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

154. The allegations in Paragraph 154 of the Complaint refer to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

155. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 155 of the Complaint and therefore deny the same. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

156. To the extent the allegations in Paragraph 156 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information

to form a belief as to the truth of the allegations in Paragraph 156 of the Complaint and therefore deny the same.

iii. PPI-Induced Chronic Kidney Disease (“CKD”)

157. To the extent the allegations in Paragraph 157 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 157 of the Complaint and therefore deny the same.

158. To the extent the allegations in Paragraph 158 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 158 of the Complaint and therefore deny the same.

159. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 159 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

160. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 160 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

161. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 161 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

162. To the extent the allegations in Paragraph 162 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 162 of the Complaint and therefore deny the same.

163. To the extent the allegations in Paragraph 163 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 163 of the Complaint and therefore deny the same. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

164. The allegations in Paragraph 164 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 164 of the Complaint and therefore deny the same.

C. PPI Products Cause Rebound Acid Hyper sensitivity, Worsening GERD and Acid Reflux, Creating Dependency

165. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 165 of the Complaint and therefore deny the same.

166. To the extent the allegations in Paragraph 166 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 166 of the Complaint and therefore deny the same.

167. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 167 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

168. To the extent the allegations in Paragraph 168 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 168 of the Complaint and therefore deny the same.

169. The allegations in Paragraph 169 of the Complaint constitute legal conclusions, to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 169 of the Complaint and therefore deny the same.

170. To the extent the allegations in Paragraph 170 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 170 of the Complaint and therefore deny the same.

171. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 171 of the Complaint and therefore deny the same. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

172. To the extent the allegations in Paragraph 172 of the Complaint call for a medical conclusion, any such response by Defendants would be premature and inappropriate. To the extent Defendants are required to respond, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 172 of the Complaint and therefore deny the same.

173. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 173 of the Complaint and therefore deny the same. Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

D. Safer Alternative to PPIs

174. To the extent the allegations in Paragraph 174 of the Complaint and its sub-parts (a) and (b) call for a medical conclusion, any such response by Defendants would be premature

and inappropriate. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 174 of the Complaint and therefore deny the same.

175. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 175 of the Complaint and therefore deny the same.

Answering further, this allegation refers to extrinsic documents not attached to or part of this Complaint, and Defendants state that such documents speak for themselves. Defendants deny the allegations to the extent they misstate or mischaracterize such documents.

176. The allegations in Paragraph 176 of the Complaint constitute legal conclusions, to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 176 of the Complaint and therefore deny the same.

E. Injuries Resulting from PPI Products

177. The allegations in Paragraph 177 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 177 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations contained in Paragraph 177 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 177 of the Complaint.

178. The allegations in Paragraph 178 of the Complaint constitute legal conclusions, to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 178 of the Complaint and therefore deny the same.

179. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 179 of the Complaint and therefore deny the same.

180. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 180 of the Complaint and therefore deny the same.

F. Defendants Actively Concealed the Dangers Associated with use of PPI Products

181. The allegations in Paragraph 181 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 181 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations contained in Paragraph 181 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 181 of the Complaint.

182. The allegations in Paragraph 182 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 182 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 182 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 182 of the Complaint.

183. The allegations in Paragraph 183 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 183 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 183 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 183 of the Complaint.

184. The allegations in Paragraph 184 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 184 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 184 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 184 of the Complaint.

185. The allegations in Paragraph 185 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 185 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 185 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 185 of the Complaint.

186. The allegations in Paragraph 186 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 186 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 186 of the Complaint are directed to Defendants, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but denies that the allegations in Paragraph 186 accurately set them forth. Defendants deny the remaining allegations in Paragraph 186 of the Complaint.

187. The allegations in Paragraph 187 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 187 of the Complaint to the extent that they

concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 1877 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 1877 of the Complaint.

188. The allegations in Paragraph 188 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 188 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 188 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 188 of the Complaint.

189. The allegations in Paragraph 189 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 189 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 189 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 189 of the Complaint.

190. The allegations in Paragraph 190 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 190 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 190 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 190 of the Complaint.

191. To the extent the allegations in Paragraph 191 of the Complaint are addressed to parties other than Defendants, no response is required. To the extent the allegations in Paragraph

191 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 191 of the Complaint and deny that Defendants had any obligation to submit proposed labeling for any PPI Product.

192. To the extent the allegations in Paragraph 192 of the Complaint are addressed to parties other than Defendants, no response is required. To the extent the allegations in Paragraph 192 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 192 of the Complaint and deny that Defendants had any obligation to submit proposed labeling for any PPI Product.

193. To the extent the allegations in Paragraph 193 of the Complaint are addressed to parties other than Defendants, no response is required. To the extent the allegations in Paragraph 193 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 193 of the Complaint and deny that Defendants had any obligation to submit proposed labeling for any PPI Product.

194. The allegations in Paragraph 194 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 194 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. Defendants are also not sure what is meant by “at all times,” as that phrase is vague and ambiguous and Defendants are unable to respond on that basis alone. To the extent the allegations contained in Paragraph 194 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 194 of the Complaint.

195. The allegations in Paragraph 195 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form

a belief as to the truth of the allegations in Paragraph 195 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 195 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 195 of the Complaint.

G. Defendants Actively Concealed the Dangers Associated with use of PPI Products

196. The allegations in Paragraph 196 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 196 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 196 of the Complaint are directed to Defendants, Defendants deny the remaining allegations in Paragraph 196 of the Complaint.

197. The allegations in Paragraph 197 of the Complaint and sub-parts (a) through (aa) constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 197 and sub-parts (a) through (aa) of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. To the extent the allegations contained in Paragraph 197 and sub-parts (a) through (aa) of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 197 and sub-parts (a) through (aa) of the Complaint. Defendants specifically deny that they had any such duties or obligations regarding any PPI Product.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

198. In response to Paragraph 198 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 198 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 198 of the Complaint.

199. The allegations in Paragraph 199 of the Complaint constitute legal conclusions, to which no response is required. Defendants specifically deny that any state statutory and common law rights and theories operate to toll or extend the statutes of limitations in any of the cases to which they are or will be named as parties. Defendants deny the remaining allegations in Paragraph 199 of the Complaint.

200. The allegations in Paragraph 200 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 200 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. Defendants also lack sufficient knowledge or information to form a belief as to what plaintiff knew or should have known and deny the allegations in Paragraph 200 on that basis. Defendants specifically deny that the discovery rule tolls the statute of limitations in any of the cases to which they are or will be named as parties and deny the remaining allegations in Paragraph 200 of the Complaint.

201. The allegations in Paragraph 201 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 201 of the Complaint. Defendants specifically deny that the discovery rule tolls the statute of limitations in any of the cases to which they are or will be named as parties and deny the remaining allegations in Paragraph 201 of the Complaint.

202. The allegations in Paragraph 202 of the Complaint constitute legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 202 of the Complaint. Defendants specifically deny that equitable tolling applies to toll the statutes of limitations in any of the cases to which they are or will be named as parties.

203. The allegations in Paragraph 203 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 203 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. Defendants also lack sufficient knowledge or information to form a belief as to what plaintiff, her medical providers, and/or her health facilities knew or should have known and deny the allegations in Paragraph 203 on that basis. Defendants deny the remaining allegations in Paragraph 203 of the Complaint.

204. The allegations in Paragraph 204 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 204 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations contained in Paragraph 204 of the Complaint are directed to Defendants, Defendants deny the allegations in Paragraph 204 of the Complaint.

205. The allegations in Paragraph 205 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 205 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. Defendants also lack sufficient knowledge or information to form a belief as to what information and data are available to or in the possession of plaintiff and/or her healthcare providers and deny the allegations in Paragraph 205 on that basis. To the extent the allegations contained in Paragraph 205 of the Complaint are directed to Defendants, Defendants deny the remaining allegations in Paragraph 205 of the Complaint.

206. The allegations in Paragraph 206 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 206 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. Defendants also lack sufficient knowledge or information to form a belief as to what plaintiff and/or her healthcare providers knew or should have known and deny the allegations in Paragraph 206 on that basis. Defendants do not know what is meant by the phrase “at the time of Plaintiff’s injuries,” as that phrase is vague and ambiguous and thus no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 206 of the Complaint and specifically deny that they committed any “wrongdoing.”

207. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 207 of the Complaint and therefore deny the same. Defendants specifically deny that they committed any “wrongdoing” or that they caused Plaintiff any injuries or damages.

208. The allegations in Paragraph 208 of the Complaint constitute legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 208 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

209. The allegations in Paragraph 209 of the Complaint constitute legal conclusions, to which no response is required. Defendants also lack sufficient knowledge or information to form a belief as to what plaintiff knew or should have known and deny the allegations in Paragraph 209 on that basis. Defendants specifically deny that the discovery rule tolls the statute of limitations in any of the cases to which they are or will be named as parties. Defendants deny the remaining allegations in Paragraph 209 of the Complaint.

210. The allegations in Paragraph 210 of the Complaint constitute legal conclusions, to which no response is required. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 210 of the Complaint to the extent that they concern parties other than Defendants and products other than their own and therefore deny the same. Defendants also lack sufficient knowledge or information to form a belief as to what Plaintiff knew or should have known and deny the allegations in Paragraph 210 on that basis. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 210 of the Complaint and specifically deny that they committed any “wrongdoing.”

211. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 211 of the Complaint. Answering further, Defendants lack sufficient knowledge or information to form a belief as to Plaintiff’s conversations with her healthcare providers. Defendants do not know what is meant by the phrase “at the time of Plaintiff’s injuries,” as that phrase is vague and ambiguous and thus no response is required. To

the extent a response is required, Defendants deny the allegations in Paragraph 211 of the Complaint.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY

212. In response to Paragraph 212 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 212 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 212 of the Complaint.

213. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2133 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 2133 of the Complaint are addressed to Defendants, the allegations in Paragraph 213 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 213 of the Complaint.

214. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 214 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 214 of the Complaint are addressed to Defendants, the allegations in Paragraph 214 of the

Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 214 of the Complaint.

215. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 215 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 215 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 215.

216. The allegations in Paragraph 216 Paragraph 263 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 216 of the Complaint.

217. The allegations in Paragraph 217 Paragraph 264 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 217 of the Complaint.

218. The allegations in Paragraph 218 Paragraph 265 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 218 of the Complaint.

219. The allegations in Paragraph 219 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 219 of the Complaint.

220. The allegations in Paragraph 220 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 220 of the Complaint.

221. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 221 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 221 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 221 of the Complaint.

222. The allegations in Paragraph 222 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 222 of the Complaint.

223. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 223 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 70 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 223 of the Complaint.

224. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 224 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 224 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but denies that the allegations in Paragraph 224 accurately set them forth. Defendants deny the remaining allegations in Paragraph 224 of the Complaint.

225. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 225 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 225 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 225 of the Complaint.

226. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 226 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 226 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 226 of the Complaint.

227. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 227 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 227 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 227 of the Complaint.

228. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 228 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 228 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants specifically

deny that they caused Plaintiff any injuries or damages. Defendants deny the remaining allegations in Paragraph 228 of the Complaint.

229. The allegations in Paragraph 229 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 229 of the Complaint.

230. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 230 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 230 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 230 of the Complaint.

231. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 231 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 231 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 231 of the Complaint.

232. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 232 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 232 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 232 of the Complaint.

233. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 233 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 233 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 233 of the Complaint.

234. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 234 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 234 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 234 of the Complaint.

235. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 235 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 235 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 235 of the Complaint.

236. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 236 of the Complaint and therefore deny the same.

237. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 237 of the Complaint and its sub-parts (a) through (f) to the extent that they concern parties other than Defendants and therefore deny the same. To the

extent the allegations in Paragraph 237 of the Complaint and its sub-parts (a) through (f) are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 237 of the Complaint and its sub-parts (a) through (f).

238. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 238 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 238 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 238 of the Complaint.

239. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 239 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 239 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 239 of the Complaint.

240. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 240 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 240 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 240 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

241. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 241 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 241 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 241 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

242. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 242 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 242 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 242 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

Defendants specifically deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 242 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

243. In response to Paragraph 243 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that plaintiffs has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest

sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 243 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 243 of the Complaint.

244. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 244 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 244 of the Complaint are addressed to Defendants, the allegations in Paragraph 244 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 244 of the Complaint.

245. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 245 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 245 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 245 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

246. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 246 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 246 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 246 of the Complaint.

247. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 247 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 247 of the Complaint are addressed to Defendants, the allegations in Paragraph 247 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 247 of the Complaint.

248. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 248 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 248 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 248 of the Complaint.

249. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 249 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 249 of the Complaint are addressed to Defendants, the allegations in Paragraph 249 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 249 of the Complaint.

250. The allegations in Paragraph 250 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 250 of the Complaint.

251. The allegations in Paragraph 251 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 251 of the Complaint.

252. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 252 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 252 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 252 of the Complaint.

253. The allegations in Paragraph 253 of the Complaint constitute medical conclusions, to which it would be premature and inappropriate to respond. To the extent a response is required, Defendants deny the allegations in Paragraph 253 of the Complaint.

254. The allegations in Paragraph 254 of the Complaint constitute medical conclusions, to which it would be premature and inappropriate to respond. To the extent a response is required, Defendants deny the allegations in Paragraph 254 of the Complaint.

255. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 255 of the Complaint and therefore deny the same.

256. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 256 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 256 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 256 of the Complaint.

257. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 257 of the Complaint and its sub-parts (a) through (e) to the extent that they concern parties other than Defendants and therefore deny the same. To the extent

the allegations in Paragraph 257 of the complaint and sub-parts (a) through (e) are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 257 of the Complaint and its sub-parts (a) through (e).

258. The allegations in Paragraph 258 of the Complaint constitute legal conclusions, to which no response is required. Answering further, Defendants do not know what is meant by “public or private product standard,” as that phrase is vague and ambiguous. To the extent a response is required, Defendants deny the allegations in Paragraph 258 of the Complaint.

259. The allegations in Paragraph 259 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 259 of the Complaint.

260. The allegations in Paragraph 260 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 260 of the Complaint.

261. The allegations in Paragraph 261 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 261 of the Complaint.

262. The allegations in Paragraph 262 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 262 of the Complaint.

263. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 263 of the Complaint to the extent they concern parties other than the Defendants. To the extent the allegations in Paragraph 263 are addressed to Defendants,

Defendants deny the allegations in Paragraph 263 of the Complaint. Defendants specifically deny that the Plaintiff is entitled to any relief, including punitive damages.

264. Defendants deny the allegations in Paragraph 264 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

265. The allegations in Paragraph 265 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 265 of the Complaint.

266. The allegations in Paragraph 266 constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 266 of the Complaint.

267. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 267 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 267 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 267 of the Complaint.

268. The allegations constitute medical conclusions, to which it would be premature and inappropriate to respond. To the extent a response is required, Defendants deny the allegations in Paragraph 268 of the Complaint.

269. Defendants lack sufficient knowledge or information to form a belief as to the allegations in Paragraph 269 of the Complaint and therefore deny the same.

270. The allegations in Paragraph 270 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 270 of the Complaint.

271. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 271 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 271 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 271 of the Complaint.

272. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 272 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 272 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 272 of the Complaint.

273. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 273 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 273 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 273 of the Complaint.

274. The allegations in Paragraph 274 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the

allegations in Paragraph 274 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

275. The allegations in Paragraph 275 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 275 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damage.

276. The allegations in Paragraph 276 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 276 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damage.

277. The allegations in Paragraph 277 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 277 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damage.

278. The allegations in Paragraph 278 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 278 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damage.

279. The allegations in Paragraph 279 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 279 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

280. The allegations in Paragraph 280 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 280 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

281. The allegations in Paragraph 281 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 281 of the Complaint.

282. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 282 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 282 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 282 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 282 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

283. In response to Paragraph 283 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 283

regarding choice of law, including of the Plaintiff's resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 283 of the Complaint.

284. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 284 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 284 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 284 of the Complaint.

285. Defendant's lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 285 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 285 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 285 of the Complaint.

286. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 286 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 286 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 286 accurately set them forth. Defendants deny the remaining allegations in Paragraph 286 of the Complaint.

287. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 287 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 287 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 287 of the Complaint.

288. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 288 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 288 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 288 accurately set them forth. Defendants deny the remaining allegations in Paragraph 288 of the Complaint.

289. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 289 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 289 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 289 of the Complaint.

290. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 290 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph

290 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 290 of the Complaint. Defendants specifically deny that they had any duty to provide warnings regarding any PPI Product.

291. The allegations in Paragraph 291 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 291 of the Complaint.

292. The allegations in Paragraph 292 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 292 of the Complaint.

293. The allegations in Paragraph 293 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 293 of the Complaint.

294. Defendants lack sufficient knowledge or information to form a belief as to how Plaintiff allegedly used the PPI Products and therefore denies such allegations in Paragraph 294 of the Complaint. Answering further, Defendants state that the remaining allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 294 of the Complaint.

295. The allegations contained in Paragraph 295 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 295 of the Complaint.

296. The allegations in Paragraph 296 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 296 of the Complaint.

297. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 297 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 297 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 297 of the Complaint.

298. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 298 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 298 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 298 of the Complaint.

299. The allegations in Paragraph 299 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 299 accurately set them forth. Defendants deny the remaining allegations in Paragraph 299 of the Complaint.

300. The allegations in Paragraph 300 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 300 of the Complaint.

301. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 301 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 301 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 301 of the Complaint. Defendants specifically deny that they had any duty to update warnings on any PPI Product.

302. The allegations in Paragraph 302 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 302 accurately set them forth. Defendants deny the remaining allegations in Paragraph 302 of the Complaint.

303. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 303 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 303 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 303 of the Complaint.

304. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 304 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 304 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 304 of the Complaint.

305. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 305 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 305 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 305 of the Complaint.

306. The allegations in Paragraph 306 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 306 of the Complaint.

307. The allegations in Paragraph 307 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 307 of the Complaint.

308. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 308 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 308 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 308 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

309. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 309 of the Complaint to the extent that they concern parties

other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 309 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 309 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

310. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 310 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 310 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 310 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

311. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 311 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 311 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 311 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

312. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 312 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 312 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph

312 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 312 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT IV
NEGLIGENCE

313. In response to Paragraph 313 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 313 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 313 of the Complaint.

314. The allegations in Paragraph 314 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 314 accurately set them forth. Defendants deny the remaining allegations in Paragraph 314 of the Complaint.

315. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 315 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph

315 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 315 of the Complaint and specifically denied that they caused Plaintiff any injuries or damages.

316. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 316 and sub-parts (a) through (z) of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 316 and sub-parts (a) through (z) of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 316 and sub-parts (a) through (z) of the Complaint. Defendants specifically deny that they owed Plaintiff any such duties regarding any PPI Product.

317. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 317 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 317 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 317 of the Complaint.

318. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 318 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 318 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 318 of the Complaint.

319. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 319 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 319 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 319 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

320. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 320 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 320 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 320 of the Complaint.

321. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 321 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 321 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 321 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

322. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 322 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 322 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 322 of the Complaint.

323. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 323 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 323 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 323 of the Complaint.

324. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 324 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 324 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 324 of the Complaint.

325. The allegations in Paragraph 325 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 325 of the Complaint. Defendants specifically deny that they caused plaintiff any injuries or damages.

326. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 326 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 326 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 326 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 326 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT V
NEGLIGENCE PER SE

327. In response to Paragraph 327 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 327 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 327 of the Complaint.

328. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 328 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 328 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 328 of the Complaint.

329. The allegations in Paragraph 329 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 329 of the Complaint.

330. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 330 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 330 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 330 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

331. The allegations in Paragraph 331 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 331 of the Complaint.

332. The allegations in Paragraph 332 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 332 of the Complaint.

333. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 333 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 333 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the

allegations in Paragraph 333 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

334. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 334 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 334 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 334 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 334 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

335. In response to Paragraph 335 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 335 regarding choice of law, includings Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 335 of the Complaint.

336. The allegations in Paragraph 336 of the Complaint constitute legal conclusions which no response is required. To the extent a response is required, Defendants admit that

applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 336 accurately set them forth. Defendants deny the remaining allegations in Paragraph 336 of the Complaint.

337. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 337 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 337 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 337 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

338. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 338 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 338 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 338 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

339. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 339 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 339 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 339 of the Complaint.

340. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 340 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 340 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 340 of the Complaint.

341. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 341 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 341 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 341 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

342. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 342 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 342 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 342 of the Complaint.

343. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 343 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 343 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 343 of the Complaint.

344. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 344 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 344 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 344 of the Complaint.

345. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 345 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 345 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 345 of the Complaint.

346. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 346 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 346 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 346 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 346 of the Complaint. In

particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

347. In response to Paragraph 347 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 347 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 347 of the Complaint.

348. The allegations in Paragraph 348 of the Complaint constitute legal conclusions which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 348 accurately set them forth. Defendants deny the remaining allegations in Paragraph 348 of the Complaint.

349. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 349 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 349 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 349 of the Complaint.

350. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 350 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 350 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 350 of the Complaint.

351. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 351 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 351 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 351 of the Complaint.

352. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 352 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 352 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 352 of the Complaint.

353. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 353 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 353 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the

allegations in Paragraph 353 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

354. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 354 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 354 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 354 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

355. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 355 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 355 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 355 of the Complaint and specifically deny that they caused plaintiff any injuries or damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 355 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT VIII
BREACH OF EXPRESS WARRANTY

356. In response to Paragraph 356 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action

enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 356 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 356 of the Complaint.

357. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 357 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 357 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 357 of the Complaint.

358. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 358 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 358 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 358 of the Complaint.

359. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 359 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 359 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 359 of the Complaint.

360. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 360 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 360 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 360 of the Complaint.

361. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 361 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 361 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 361 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

362. The allegations in Paragraph 362 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 362 of the Complaint.

363. The allegations in Paragraph 363 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 363 of the Complaint.

364. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 364 of the Complaint and its sub-parts (a) through (d) to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 364 of the Complaint and its sub-parts (a) through (d) are

addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 364 of the Complaint and its sub-parts (a) through (d).

365. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 365 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 365 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 365 of the Complaint.

366. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 366 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 366 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 366 of the Complaint.

367. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 367 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 367 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 367 of the Complaint.

368. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 368 of the Complaint to the extent that they concern parties

other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 368 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 368 of the Complaint.

369. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 369 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 369 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 369 of the Complaint.

370. The allegations in Paragraph 370 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 370 of the Complaint.

371. The allegations in Paragraph 371 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 371 of the Complaint.

372. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 372 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 372 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 372 of the Complaint.

373. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 373 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 373 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 373 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

374. The allegations in Paragraph 374 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 374 of the Complaint, Defendants specifically deny that they caused Plaintiff any injuries or damages.

375. The allegations in Paragraph 375 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 375 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 375 of the Complaint. In particular, Defendants deny that plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT IX
BREACH OF IMPLIED WARRANTY

376. In response to Paragraph 376 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the

Complaint. Defendants deny that plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 376 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 376 of the Complaint.

377. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 377 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 377 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 377 of the Complaint.

378. The allegations in Paragraph 378 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 378 of the Complaint.

379. The allegations in Paragraph 379 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 379 of the Complaint.

380. The allegations in Paragraph 380 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 380 of the Complaint.

381. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 381 of the Complaint to the extent that they concern parties

other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 381 of the Complaint are addressed to Defendants, the allegations in Paragraph 381 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 381 of the Complaint.

382. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 382 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 382 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 382 of the Complaint.

383. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 383 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 383 of the Complaint are addressed to Defendants, the allegations in Paragraph 383 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 383 of the Complaint.

384. The allegations in Paragraph 384 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 384 of the Complaint.

385. The allegations in Paragraph 385 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 385 of the Complaint.

386. The allegations in Paragraph 386 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 386 of the Complaint.

387. The allegations in Paragraph 387 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 387 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

388. The allegations in Paragraph 388 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 388 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

389. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 389 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 389 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 389 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 389 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT X
NEGLIGENT MISREPRESENTATION

390. In response to Paragraph 390 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff have adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 390 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 390 of the Complaint.

391. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 391 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 391 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 391 of the Complaint.

392. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 392 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 392 of the Complaint are addressed to Defendants, the allegations in Paragraph 392 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 392 accurately set them forth. Defendants deny the remaining allegations in Paragraph 392 of the Complaint.

393. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 393 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 393 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 393 of the Complaint.

394. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 394 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 394 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 394 of the Complaint.

395. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 395 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 395 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 395 of the Complaint.

396. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 396 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 396 of the Complaint are addressed to Defendants, the allegations in Paragraph 396 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 396 of the Complaint.

397. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 397 of the Complaint to the extent that they concern parties

other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 397 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 397 of the Complaint.

398. The allegations in Paragraph 398 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 398 of the Complaint.

399. The allegations in Paragraph 399 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 399 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

400. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 400 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 400 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 400 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants also deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 400 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT XI
FRAUD AND FRAUDULENT MISREPRESENTATION

401. In response to Paragraph 401 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the

Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 401 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 401 of the Complaint.

402. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 402 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 402 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 402 of the Complaint.

403. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 403 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 403 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 403 of the Complaint.

404. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 404 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 404 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 404 of the Complaint.

405. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 405 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 405 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 405 of the Complaint.

406. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 406 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 406 of the Complaint.

407. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 407 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 407 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 407 of the Complaint.

408. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 408 of the Complaint and therefore deny the same.

Defendants specifically deny that they made any false or misleading representations.

409. The allegations in Paragraph 409 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 409 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

410. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 410 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 410 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 410 of the Complaint.

411. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 411 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 411 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 411 of the Complaint.

412. The allegations in Paragraph 412 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 412 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

413. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 413 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 413 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 413 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants further deny that plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 413 of the Complaint. In particular, Defendants deny that plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT XII
Gross Negligence

414. In response to Paragraph 414 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 414 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 414 of the Complaint.

415. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 415 of the Complaint and its sub-parts (a) through (b) to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 415 of the Complaint and its sub-parts (a) through (b) are

addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 415 of the Complaint and its sub-parts (a) through (b).

416. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 416 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 416 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 416 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants further deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 416 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT XIII
FRAUDULENT CONCEALMENT

417. In response to Paragraph 417 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 417 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 417 of the Complaint.

418. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 418 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 418 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 418 of the Complaint.

419. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 419 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, To the extent the allegations in Paragraph 419 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph 419 of the Complaint.

420. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 420 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 420 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 420 of the Complaint.

421. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 421 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 421 of the Complaint are addressed to Defendants, Defendants deny the allegations in Paragraph

421 of the Complaint. Defendants specifically deny that they made any false or misleading representations.

422. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 422 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 422 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 422 of the Complaint.

423. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 423 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 423 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny that the allegations in Paragraph 423 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

424. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 424 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 424 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 424 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

425. The allegations in Paragraph 425 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 425 accurately set them forth. Defendants deny the remaining allegations in Paragraph 425 of the Complaint.

426. The allegations in Paragraph 426 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 426 accurately set them forth. Defendants deny the remaining allegations in Paragraph 426 of the Complaint.

427. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 427 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 427 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants admit that applicable law imposes certain duties on pharmaceutical manufacturers but deny that the allegations in Paragraph 427 accurately set them forth. Defendants deny the remaining allegations in Paragraph 427 of the Complaint.

428. The allegations in Paragraph 428 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 428 of the Complaint.

429. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 429 of the Complaint to the extent that they concern parties

other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 429 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 429 of the Complaint. Defendants specifically deny that they owed Plaintiff any duty to warn regarding any PPI Product.

430. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 430 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 430 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 430 of the Complaint. Defendants specifically deny that they owed Plaintiff any duty to warn regarding any PPI Product.

431. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 431 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 431 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 431 of the Complaint. Defendants specifically deny that they owed Plaintiff any duty to warn or instruct regarding any PPI Product.

432. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 432 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 432 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 432 of the Complaint.

433. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 433 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 433 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 433 of the Complaint and specifically deny that they caused Plaintiff any injuries or damages.

434. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 434 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 434 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 434 of the Complaint.

435. The allegations in Paragraph 435 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 435 of the Complaint.

436. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 436 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 436 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 436 of the Complaint.

437. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 437 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 437 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 437 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

438. The allegations in Paragraph 438 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 438 of the Complaint.

439. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 439 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 439 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 439 of the Complaint.

440. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 440 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 440 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 440 of the Complaint.

441. The allegations in Paragraph 441 of the Complaint constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 441 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in the first paragraph immediately following Paragraph 441 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in the first paragraph immediately following Paragraph 441 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in the first paragraph immediately following Paragraph 441 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that Plaintiff is entitled to punitive damages.

Defendants further deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph, or the second paragraph immediately following Paragraph 441 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

442. In response to Paragraph 442 of the Complaint, Defendants incorporate by reference their responses to the allegations in all preceding and succeeding paragraphs of the

Complaint. Defendants deny that Plaintiff has adequately pled any of the causes of action enumerated in the Complaint and deny that such allegations are to be read “in the broadest sense” rather than in a reasonable and appropriate sense. The allegations in Paragraph 442 regarding choice of law, including of the Plaintiff’s resident state are legal conclusions to which no response is required. Defendants deny the remaining allegations in Paragraph 442 of the Complaint.

443. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 443 of the Complaint regarding Plaintiff’s use of PPI Products and therefore deny the same. The allegations in Paragraph 443 of the Complaint that PPI Products caused Plaintiff’s “ascertainable losses” constitutes a legal conclusion, to which no response is required. To the extent a response is required, Defendants deny such allegation and deny all remaining allegations in Paragraph 443 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

444. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 444 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 444 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 444 of the Complaint.

445. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 445 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 445 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to

which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 445 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages.

446. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 446 of the Complaint to the extent that they concern parties other than Defendants and therefore deny the same. To the extent the allegations in Paragraph 446 of the Complaint are addressed to Defendants, the allegations constitute legal conclusions, to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 446 of the Complaint. Defendants specifically deny that they caused Plaintiff any injuries or damages and, in particular, deny that plaintiff is entitled to punitive damages.

Defendants further deny that Plaintiff is entitled to any of the relief sought in the “WHEREFORE” paragraph immediately following Paragraph 446 of the Complaint. In particular, Defendants deny that Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

PRAYER FOR RELIEF

With respect to the allegations in the second unnumbered paragraph following Paragraph 446 of the Complaint and its subparts a – h, which are under the caption “**PRAYER FOR RELIEF**” and begin with the words “WHEREFORE, Plaintiff demands judgment,” Defendants deny that the Plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs or any other relief whatsoever.

447. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

SEPARATE DEFENSES

Discovery, to the extent any is permissible under applicable law, and investigation may reveal that one or more of the following defenses should be available to Defendants in this matter. Defendants accordingly preserve the right to assert these separate defenses. Upon completion of discovery, if facts warrant, Defendants may withdraw any of these defenses as may be appropriate. Defendants further reserve the right to amend this Answer to assert additional defenses and other claims as discovery proceeds.

By alleging the matters set forth below, Defendants do not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, nothing stated herein is intended or shall be construed as an acknowledgment that any particular issue or subject necessarily is relevant to Plaintiff's allegations.

If necessary and/or in the alternative, Defendants raise the following defenses available in Ohio whose laws might be deemed controlling in this case, but reserve the right to amend its Answer to raise any additional defenses which they may have against Plaintiff's claims:

1. The Complaint, in whole or part, fails to state a claim or cause of action against Defendants upon which relief can be granted.
2. The Complaint fails to state a claim or claims upon which relief can be granted due to lack of adequate product identification.
3. Plaintiff fails to plead her claims against Defendants with sufficient particularity as required by Ohio Rules of Civil Procedure.
4. All claims against defendants other than Novartis Corporation, NPC, NIBRI, and NV&D are improperly joined or fraudulently joined in this action.

5. Plaintiff has filed this suit in an improper or inconvenient venue and the case should be dismissed under the doctrine of *forum non conveniens* and/or transferred to a proper and/or more convenient venue, if any. If transfer to a proper and/or more convenient forum is not available, Plaintiff's claims must be dismissed.

6. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing and/or capacity to assert them.

7. This Court and the Court in which this suit was filed lacks personal jurisdiction over Defendants with respect to Plaintiff's claims, and thus the Complaint must be dismissed.

8. This Court and the Court in which this suit was filed lack personal jurisdiction over Defendants pursuant to the Supreme Court's ruling in *Daimler AG v. Bauman* and its progeny.

9. This Court and the Court in which this suit was filed lack personal jurisdiction over Defendants pursuant to the Supreme Court's rulings in *Walden v. Fiore* and *Bristol-Myers Squibb Co. v. Superior Court* and their progeny.

10. Plaintiff's claims against Defendants must be dismissed because of insufficient process, including under all applicable international laws and treaties, including but not limited to the Hague Convention.

11. Plaintiff's claims against Defendants must be dismissed because of insufficient service of process, including under all applicable international laws and treaties, including but not limited to the Hague Convention.

12. The doctrines contained in Restatement (Second) of Torts § 402A, Comments J and K, and the comparable provisions of the Restatement (Third) of Torts (Products Liability) bar plaintiff's claims against Defendants in whole or in part.

13. Defendants assert any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

14. Plaintiff's claims are barred in whole or in part by applicable statutes of limitations or repose and/or the doctrines of laches, estoppel, and/or waiver.

15. Plaintiff's claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

16. Plaintiff's claims are barred because Defendants are not current or former manufacturers, developers, or sellers of any of the PPI Products identified in the Complaint, which Plaintiff alleges were the proximate cause of their injuries and damages.

17. There was no defect in the products at issue with the result that Plaintiff is not entitled to recover against Defendants.

18. There was no causal connection between any alleged defect in the products at issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover against Defendants.

19. Plaintiff's claims are barred in whole or in part by Plaintiff's misuse or abnormal use of the products or failure to follow instructions.

20. The alleged injuries to Plaintiff were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by persons other than Defendants.

21. Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

22. Any alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

23. Plaintiff's claims are barred by their use of product for "off-label" purposes.

24. Plaintiff's claims are barred by the "learned intermediary" doctrine.

25. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

26. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in conformance with industry custom/usage standards and/or legislative/administrative/regulatory standards.

27. If it should be proven that any product distributed by Defendants was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that the Defendants neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

28. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

29. Plaintiff's claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA. *See, e.g.,* N.J.S.A. §§ 2A:58C-4, -5 (to the extent New Jersey law applies).

30. To the extent that New Jersey law applies, Plaintiff's claims are subsumed and/or barred by the New Jersey Products Liability Act, in whole or in part. *See Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 54-55, 948 A.2d 587, 589 (N.J. 2008); *In re Lead Paint Litig.*, 191 N.J. 405, 436-37, 924 A.2d 484, 503-04 (N.J. 2007); *Brown ex rel. Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 515-18 (D.N.J. 2002).

31. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

32. Plaintiff's claims are preempted, in whole or in part, under the Supremacy Clause of the United States Constitution, Article IV, clause 2, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of pharmaceutical products.

33. Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or

independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical conditions.

34. If Plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which Defendants are neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product developed, sold, or manufactured by Defendants. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiff's alleged injury or damages.

35. Plaintiff's alleged damages are a direct and proximate result of their own negligence or other conduct, and such conduct is the cause of their injuries and thus Plaintiff's recovery is barred, or reduced in proportion to Plaintiff's own negligence, by the doctrine of comparative fault and/or comparative negligence and/or contributory negligence. Further, to the extent Plaintiff's injuries were caused by others, including but not limited to the co-Defendants in this case, those individuals or entities shall be responsible to the extent they caused or contributed to Plaintiff's injuries.

36. Defendants are not jointly and severally liable for any damages recoverable to the extent that such damages result from the conduct of parties other than Defendants, no fault, damages, or other admissions being made.

37. Plaintiff's claims are barred, in whole or in part, because plaintiff alleged injuries, if caused by any product for which Defendants are responsible, which is denied, were the result of Plaintiff's own idiosyncratic reactions and/or pre-existing conditions.

38. Plaintiff failed to mitigate, which limits Plaintiff's damages, if any, in whole or in part.

39. Any product for which Defendants are responsible was fit and proper for its intended purposes and the social utility of the drug outweighed any possible risk inherent in its use.

40. The Plaintiff's product liability claims are barred because the benefits of the products outweighed their risks.

41. Any alternative design alleged by Plaintiff was not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

42. Defendants have no legal relationship or privity with Plaintiff and owe no duty to Plaintiff by which liability could be attributed to it.

43. The claims of Plaintiff should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

44. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

45. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

46. To the extent Plaintiff asserts a claim for breach of implied warranty, such claim must fail because the products were not used for their ordinary purpose.

47. Defendants plead all affirmative defenses under the Uniform Commercial Code (“UCC”) now existing or which may arise in the future, including but not limited to UCC §§ 2-607 and 2-709.

48. Notwithstanding the claims and contentions of Plaintiff, Plaintiff received all or substantially all of the benefit from the products that Plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Defendants must be correspondingly reduced.

49. Plaintiff’s causes of action are barred in whole or in part by Plaintiff’s own contributory/comparative negligence.

50. Plaintiff’s recovery, if any, shall be reduced by those payments that Plaintiff receives from collateral sources.

51. If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Defendants’ product.

52. Plaintiff’s claims are barred, in whole or in part, because any labeling, advertisements, or marketing by Defendants is protected commercial speech under the First Amendment of the United States Constitution.

53. Plaintiff’s claims and/or plaintiff’s right to recover damages, no liability, damages, or other admissions being made, are limited or barred by applicable survival statutes, wrongful death statutes, or other applicable statutes or law limiting claims or damages after the death of the person(s) allegedly injured by the Defendants.

54. Plaintiff’s right to recover damages, no right to recover damages being admitted, is limited in whole or part, to damages incurred prior to the death of decedents.

55. Plaintiff's claims for punitive damages are barred because such an award would violate Defendants' due process, equal protection and/or other rights under the United States Constitution and, to the extent applicable, the Ohio State Constitution. To the extent that the Plaintiff asserts a claim for punitive damages, that claim is in contravention of the rights of the Defendants under the following constitutional provisions:

- a. Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the Ohio State Constitution, on grounds including the following:
- b. it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- c. the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution;
- d. the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby

violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution;

- e. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution;
- f. the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution;
- g. the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Ohio State Constitution;
- h. the award of punitive damages to the Plaintiff in this action would constitute a deprivation of property without due process of law; and
- i. the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

56. To the extent Plaintiff asserts a demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of

BMW of No. America v. Gore, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008) and their progeny as well as other similar cases under both federal and state law.

57. Plaintiffs' claims for punitive damages are barred because Plaintiff has failed to allege conduct warranting imposition of punitive damages under, to the extent applicable, Ohio state law.

58. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

59. Plaintiff's claims for punitive damages are preempted, in whole or in part, by applicable federal law.

60. To the extent that New Jersey law applies to Plaintiff's claim, Plaintiff is limited in the amount, if any, they may recover for punitive damages under N.J.S.A. § 2A:15-5.9, *et seq.*

61. To the extent that New Jersey law applies to Plaintiff's claim, Plaintiff is barred from recovering punitive damages under N.J.S.A. § 2A:58C-5(c) because the product was subject to pre-market approval by the FDA, was approved by the FDA, and/or was generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

62. Punitive damages against Defendants cannot be recovered based on alleged fraudulent representation to the FDA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *see also* N.J.S.A. § 2A:58C-5(c); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 949 A.2d 223 (App. Div. 2008).

63. Plaintiff's claims for punitive damages are barred in whole or in part because Plaintiff is not entitled to compensatory damages, no fault or other admissions being made.

64. Plaintiff's claims based on fraud, misrepresentation or suppression are preempted in whole or in part. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001).

65. Plaintiff's claims based on fraud, misrepresentation or suppression are barred by plaintiff's failure to plead their claim with reasonable particularity as required by applicable court pleading rules and applicable state statutory and/or common law.

66. Plaintiff's claims based on fraud, misrepresentation or suppression are barred by Plaintiff's failure to allege an "ascertainable loss." *See, e.g., N.J.S.A. § 56:8 et seq.* (to the extent that New Jersey law is applicable).

67. Defendants are entitled to the benefit of, and hereby claim, all defenses and presumptions available to it pursuant to any applicable Product Liability Act.

68. Defendants are entitled to the benefit of, and hereby claim, all defenses and presumptions available to it pursuant to any applicable consumer protection or unfair trade practices statutes.

69. Plaintiff's claims are barred to the extent that Plaintiff seeks relief under laws of states that do not govern Plaintiff's claims.

70. Defendants incorporate by reference each defense asserted by any other defendant in this litigation.

71. Defendants hereby give notice that they intend to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserve their right to amend this Answer to assert such defenses.

Defendants also assert the following defenses:

1. Plaintiff's claims are barred and/or preempted by the provisions of the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81, and Defendants hereby assert all allowable limitations and defenses under the Ohio Products Liability Act.
2. Defendants hereby plead all available defenses and principles as set forth in Ohio Rev. Code Ann. §§ 2307.22-2307.29.
3. Plaintiff's claims are barred because any products for which Defendants are responsible are "ethical drugs" as defined by Ohio Rev. Code Ann. § 2307.71(A)(4), and adequate warnings and instructions were provided concerning all unavoidably unsafe aspects, if any, of the product at issue.
4. Plaintiff's claims are barred, in whole or in part, by Ohio's contributory and/or comparative principles set forth in O.R.C. §§ 2315.22, *et seq.* and 2315.32-2315.36.
5. Plaintiff's recovery as against Defendants should be barred in accordance with Ohio Rev. Code Ann. § 2307.78.
6. Plaintiff's damages demands are subject to any and all applicable limitations under Ohio law, including but not limited to those contained in Ohio Rev. Code Ann. §§ 2315.18 and 2315.21.
7. Plaintiff's right to recover damages, if any, is statutorily limited by Ohio's wrongful death statute, Ohio Rev. Code Ann. §§ 2125.01 through 2125.04.
8. Plaintiff's claims for punitive or exemplary damages as set forth in the complaint are barred by Ohio Rev. Code Ann. § 2307.80(C).
9. Plaintiff's claims under Ohio's consumer protection statute are preempted by the Ohio Products Liability Act, Ohio Rev. Code Ann. §§ 2307.71 through 2307.81.

10. Ohio's Consumer Sales Practices Act, Ohio Rev. C. §1345.12(C), specifically precludes claims for personal injury or death.

11. Plaintiff fails to state a claim for relief under Ohio Rev. Code Ann. §§ 1345.01, *et seq.*

12. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the applicable state constitution.

13. Plaintiff's claims are barred in whole or in part because Ohio Rev. Code Ann. §§ 1345.01, *et seq.* unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

14. Plaintiff's claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in Ohio Revised Code § 2307.711.

15. All or part of the injuries or damages alleged in Plaintiff's Complaint were caused by the acts and omissions of another or others, whose conduct Defendants had no reason to anticipate and for whose conduct Defendants is not and were not responsible. Ohio Revised Code § 2307.22, *et seq.*

16. The injuries or damages of which Plaintiff complains were caused or contributed to by one or more persons from whom the Plaintiff does not seek recovery in this action. Ohio Revised Code § 2307.23.

17. One or more of Plaintiff's claims are barred by the tort reform provisions of Ohio law set forth in Ohio Senate Bill 120, Senate Bill 281, and Senate Bill 80, including but not

limited to the limitations and prohibitions on certain types of claims, and the limitations (caps) on compensatory and punitive damages set forth therein, including but not limited to Ohio Revised Code §§ 2307.71 through 2307.80, § 2315.18, § 2315.21, et al.

18. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(D) because adequate warning and instruction were provided under Ohio Revised Code § 2307.76 concerning any unavoidably unsafe aspects of the product.

19. Plaintiff's design defect claims fail under Ohio Revised Code § 2307.75(E) because the alleged risk of which Plaintiff complains is unavoidable and/or an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the usefulness or desirability of the product.

20. Plaintiff's design defect claims fail because a practical and technically feasible alternative design or formulation was not available as provided under Ohio Revised Code § 2307.75(F).

21. Plaintiff's inadequate warning claims are barred under Ohio Revised Code § 2307.76(B) because the alleged risk of which he claims is open, obvious, and/or a matter of common knowledge.

* * *

WHEREFORE, Defendants demand judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY DEMAND

Defendants demand a jury trial as to all issues so triable.

Dated: August 6, 2019

Respectfully submitted,

/s/ Joyce D. Edelman

Joyce D. Edelman (0023111)

Ryan L. Graham (0093826)

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*Attorney for Defendants Novartis Corporation, Novartis
Pharmaceuticals Corporation, Novartis Institutes for
Biomedical Research, Inc. and Novartis Vaccines and
Diagnostics, Inc.*

CERTIFICATE OF SERVICE

I certify that pursuant to Rule 5(B)(3) of the Ohio Rules of Civil Procedure, I electronically filed the foregoing on August 6, 2019 using the Clerk's e-filing system, which system will send electronic notification constituting service on the following counsel who have appeared in the matter:

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/s/ Joyce D. Edelman

Joyce D. Edelman (0023111)



D126432086

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA A. BEHYMER

Plaintiff,

v.

ABBOTT LABORATORIES, et al.

Defendants.

CASE NO. A 1902638

JUDGE SYLVIA S. HENDON

FILED

CLERK OF COURTS
HAMILTON COUNTY, OH
COMMON PLEAS
2019 AUG 26 P 12:49

MOTION FOR PERMISSION TO APPEAR PRO HAC VICE

Pursuant to Gov. Bar R. XII(2)(A)(6), James R.M. Hemmings, attorney for Defendants, hereby moves the Hamilton County Court of Common Pleas to grant his permission to appear pro hac vice and participate as counsel in this case for Abbott Laboratories; Takeda Pharmaceuticals U.S.A., Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceutical Company Limited.

Movant represents that the following is a list of the jurisdictions in which he has ever been licensed to practice law, including dates of admission to practice, resignation, or retirement, and any attorney registration numbers:

Jurisdiction	Admission Date	Registration No.
Missouri	September 17, 2003	55133
Kansas	April 30, 2004	21481
Illinois	November 10, 2005	6286380
Wisconsin	July 19, 2013	1093351



VERIFY RECORD

Movant represents that he has not been granted permission to appear pro hac vice in more than three proceedings before Ohio tribunals in the current calendar year pursuant to Gov.Bar R. XII(2)(A)(5).

Jennifer L. Steinmetz, an active Ohio attorney in good standing, has agreed to associate with Movant on this case.

The affidavit required by Gov.Bar R. XII(2)(A)(6), a copy of Movant's certificate of pro hac vice registration furnished by the Supreme Court of Ohio Office of Attorney Services, and a certificate indicating service of this Motion on all known parties and attorneys of record are attached. Movant understands that, if this Motion is granted, Movant must file a Notice of Permission to Appear Pro Hac Vice and a copy of the Order granting permission with the Supreme Court of Ohio Office of Attorney Services within thirty days of the Order.


Respectfully submitted,



James R.M. Hemmings
PHV-21425-2019
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Facsimile: (312) 624-6309
james.hemmings@tuckerellis.com

CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2019, the foregoing **Motion for Permission to Appear Pro Hac Vice** was filed electronically and that a copy has been served upon counsel of record by the court's electronic filing system.



James R. M. Hemmings
PHV-21425-2019

THE SUPREME COURT *of* OHIO

OFFICE OF ATTORNEY SERVICES

IN THE MATTER OF THE APPLICATION OF

James Hemmings

FOR PRO HAC VICE REGISTRATION

per Gov. Bar R. XII, Section 2(A)(3)

Certificate of
PRO HAC VICE
REGISTRATION

2019

Registration Number:
PHV- 21425-2019

James Hemmings

, having met the requirements of, and found to be in full compliance with, Section 2(A)(3) of Rule XII of the Rules for the Government of the Bar of Ohio, is hereby issued this certificate of pro hac vice registration in the state of Ohio.

To receive permission to appear pro hac vice in an Ohio proceeding, a motion requesting such permission must be filed with the tribunal in accordance with Section 2(A)(6) of Rule XII of the Rules for the Government of the Bar of Ohio.



Gina White Palmer
Director, Attorney Services

Expires December 31, 2019

THE SUPREME COURT of OHIO

OFFICE OF ATTORNEY SERVICES

IN THE MATTER OF THE APPLICATION OF

James Richard Moreau Hemmings

AFFIDAVIT OF APPLICANT
Gov. Bar R. XII, Section 2(A)(3)

FOR PRO HAC VICE REGISTRATION

James Richard Moreau Hemmings

_____, being first duly cautioned, swears or affirms as follows:

- a. I have never been disbarred from the practice of law.
- b. I have been admitted to the practice of law in the following jurisdictions (attach additional page if necessary):

Kansas

Missouri

Wisconsin

Illinois

- c. Choose one:

- ☒ I am not currently suspended from the practice of law in any jurisdiction where I have been admitted to practice.
- ☐ I am currently suspended from the practice of law in the following jurisdictions:

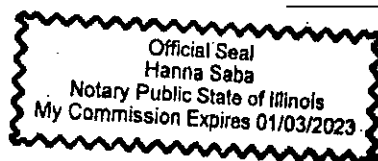
- d. Choose one:

- ☒ I have not resigned from the practice of law with discipline pending in any jurisdiction where I have been admitted to practice.
- ☐ I have resigned from the practice of law with discipline pending in the following jurisdiction(s):

SIGNATURE OF APPLICANT

Sworn to or affirmed before me and subscribed in my presence the 5th day of August, 2019, in the state of Illinois and county of Cook.

*Notary public's stamp/seal and commission expiration date are required.



SIGNATURE OF NOTARY PUBLIC*

ENTERED

OCT 23 2019

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA A. BEHYMER

:

Case No. A1902638

Plaintiff

:

Judge Sylvia S. Hendon

v.

:

ABBOTT LABORATORIES, et al.

:

ENTRY GRANTING MOTION
TO APPEAR PRO HAC VICE

Defendants

:

THIS MATTER COMES BEFORE THE COURT ON THE MOTION OF James R.M.
Hennings, attorney for Defendants to appear *pro hac vice* and participate as counsel in this
case.

For good cause shown, the motion is hereby granted.



D127002939

A handwritten signature in black ink, appearing to read 'Sylvia S. Hendon', written over a horizontal line.

Sylvia S. Hendon, Judge
October 23, 2019



VERIFY RECORD

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

TERESA A. BEHYMER	:	CASE NO. A1902638
	:	
Plaintiff,	:	JUDGE SYLVIA HENDON
	:	
-VS-	:	NOTICE OF DISMISSAL OF
	:	DEFENDANTS THE PROCTER &
ABBOTT LABORATORIES, et al.	:	GAMBLE COMPANY AND THE
	:	PROCTER & GAMBLE
Defendants.	:	MANUFACTURING COMPANY <u>ONLY</u>
	:	WITHOUT PREJUDICE

Notice is hereby given that Plaintiff is dismissing the Defendants, The Procter & Gamble Company and The Procter & Gamble Manufacturing Company, only, without prejudice, pursuant to Civ. R. 41(a), with all remaining claims against all remaining Defendants to stay in full force and effect.

Respectfully submitted,

/s/ John D. Holschuh, Jr.
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*Attorney for The Procter & Gamble
Company and the Procter & Gamble
Manufacturing Company*



VERIFY RECORD

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was sent via electronic mail this 9th day of October, 2020 upon the following:

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The Procter & Gamble Manufacturing Company*

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Attorney for Takeda Defendants

/s/ John D. Holschuh, Jr.

John D. Holschuh, Jr.

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